UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

TOWN OF WEYMOUTH

Plaintiff,

v.

PURDUE PHARMA L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901,

PURDUE PHARMA, INC.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901,

THE PURDUE FREDERICK COMPANY INC.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901,

TEVA PHARMACEUTICALS USA, INC.
190 Horsham Road
North Wales, PA 19454,

CEPHALON, INC.
41 Moores Road
Frazer, PA 19355,

JOHNSON & JOHNSON
CT Corporation System
101 Federal Street
Boston, MA 02110,

JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA,

Civil Action No.:

COMPLAINT

(Jury Trial Demanded)

INC. n/k/a JANSSEN
PHARMACEUTICALS, INC.
c/o CT Corporation System
600 N 2nd Street, Suite 401
Harrisburg, Pennsylvania 17101-1071,

ENDO HEALTH SOLUTIONS INC.
c/o CT Corporation System
155 Federal Street Suite 700
Boston, MA 02110,

ENDO PHARMACEUTICALS, INC.
c/o CT Corporation System
155 Federal Street Suite 700
Boston, MA 02110,

CARDINAL HEALTH INC.
c/o CT Corporation System
155 Federal Street Suite 700
Boston, MA 02110,

MALLINCKRODT LLC
c/o CT Corporation System
155 Federal Street Suite 700
Boston, MA 02110,

MALLINCKRODT PLC
675 McDonnell Blvd.
St. Louis, MO 63042,

MALLINCKRODT BRAND
PHARMACEUTICALS, INC.
675 McDonnell BLV
St. Louis, MO 63042,

SPECGX, LLC
385 Marshall Avenue
Webster Groves, MO
63119,

MCKESSON CORPORATION
c/o Corporation Service Company
84 State St.
Boston, MA 02109,

AMERISOURCEBERGEN DRUG

CORPORATION
c/o CT Corporation System
c/o CT Corporation System
155 Federal Street Suite 700
Boston, MA 02110,

WALGREENS BOOTS ALLIANCE
d/b/a WALGREEN CO
d/b/a Walgreens of Massachusetts, LLC
c/o Corporation Service Company
84 State Street
Boston, MA 02109,

AND

JANE DOES 1 – 50,

Defendants.

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I. PRELIMINARY STATEMENT

1. Plaintiff city known as the Town of Weymouth, Massachusetts ("Weymouth"), like many other jurisdictions across the country, is struggling with an opioid crisis. Unlike the crack cocaine epidemic, this drug crisis began with a corporate business plan. It started with a decision by Purdue Pharma L.P., and its corporate family (collectively, "Purdue"), to promote opioids deceptively and illegally in order to significantly increase sales and generate billions of

dollars in revenue for Purdue's private owners, the Sackler family. Unfortunately, Purdue's strategies were quickly joined by Endo Pharmaceuticals Inc., Endo Health Solutions Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc. Ortho-McNeil-Janssen Pharmaceuticals, Inc. N/K/A Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc. N/K/A Janssen Pharmaceuticals, Inc., Teva Pharmaceuticals USA, Inc., Mallinckrodt plc, SpecGX LLC, Mallinckrodt Brand Pharmaceuticals, Inc. and Mallinckrodt LLC (collectively with Purdue, "Manufacturing Defendants"), used misrepresentations regarding the risks and benefits of opioids to enable the widespread prescribing of opioids for common, chronic pain conditions like low back pain, arthritis, and headaches.[1] In addition, the Manufacturing Defendants, along with McKesson Corporation, AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and Walgreens Boots Alliance d/b/a Walgreen Co. failed to maintain effective controls, and to investigate, report, and take steps to terminate suspicious orders. As a direct consequence, the rampant use, overuse, and abuse of opioids has overwhelmed much of the country, including in Weymouth and its residents.

2. Weymouth, Massachusetts brings this action to redress these Defendants' campaign of unfairly, deceptively, and fraudulently marketing and promoting opioids.

3. Manufacturing Defendants manufacture, market, and sell prescription opioid pain medications, including the brand-name drugs OxyContin, Butrans, Hysingla ER, Actiq, Fentora, Opana/Opana ER, Percodan, Percocet, Zydone, Subsys, Xartemis XR, Exalgo, Nucynta/Nucynta ER, and Duragesic, and generic drugs such as oxycodone.

[1] Consistent with the commonly accepted medical usage, the term "chronic pain" as used herein refers to non-cancer pain lasting three months or longer.

4. Distributor Defendants McKesson Corporation d/b/a McKesson Drug Company, AmerisourceBergen Drug Corporation, Walgreens Boots Alliance d/b/a Walgreens Co., and Cardinal Health, Inc. distribute opioid medications, including the medications listed above, to pharmacies, pain clinics and other dispensaries across the country and in Weymouth.

5. Prescription opioids are narcotics. They are derived from and possess properties similar to opium and heroin, and they are regulated as controlled substances. While opioids can dampen the perception of pain, they also can create an addictive, euphoric high. At higher doses, they can slow the user's breathing, causing potentially fatal respiratory depression. Most patients receiving more than a few weeks of opioid therapy will experience withdrawal symptoms—including severe anxiety, nausea, headaches, tremors, delirium, and pain—which are often prolonged, if opioid use is delayed or discontinued. When using opioids continuously, patients grow tolerant to their analgesic effects (i.e. to relief of pain)—requiring progressively higher doses and increasing the risks of withdrawal, addiction, and overdose.

6. Because the medical community recognized these dangers, they originally used opioids cautiously and sparingly, typically only for short-term acute pain—where brief use limited the need for escalating doses and the risk of addiction—or for palliative (end-of-life) care. Consequently, the market for prescription opioids was sharply constrained.

7. As Purdue developed OxyContin in the mid-1990s, it knew that to expand its market and profits, it needed to change the perception of opioids to permit and encourage the use of opioids long-term for widespread chronic conditions like back pain, migraines, and arthritis. Purdue, joined by Teva, Janssen, Endo, Mallinckrodt began to promote opioids generally, and their own opioids in particular, as safe, effective, and appropriate for even long-term use for routine pain conditions. As part of this strategy, Manufacturing Defendants misrepresented the

risk of addiction for pain patients as modest, manageable, and outweighed by the benefits of opioid use.

8. From the day they made the pills to the day those pills were consumed in our communities, these Manufacturing Defendants had control over the information regarding addiction they chose to spread and emphasize as part of their massive marketing campaign. By providing misleading information to doctors about addiction being rare and opioids being safe even in high doses, then pressuring them into prescribing their products by arguing, among other things, that no one should be in pain, the Manufacturing Defendants created a population of addicted patients who sought opioids at never-before-seen rates. The scheme worked, and through it the Manufacturing Defendants caused their profits to soar as more and more people became dependent on opioids.

9. On the supply side, the crisis was fueled and sustained by those involved in the supply chain of opioids, including manufacturers and distributors, (together, "Defendants"), who failed to maintain effective controls over the distribution of prescription opioids, and who instead have actively sought to evade such controls. Defendants have contributed substantially to the opioid crisis by selling and distributing far greater quantities of prescription opioids than they know could be necessary for legitimate medical uses, while failing to report, and to take steps to halt suspicious orders when they were identified, thereby exacerbating the oversupply of such drugs and fueling an illegal secondary market.

10. As many as 1 in 4 patients who receive prescription opioids long-term for chronic pain in primary care setting struggles with addiction. In 2014, almost 2 million Americas were addicted to prescription opioids and another 600,000 to heroin. From 1999 to 2015, more than 183,000 people died in the U.S. from overdoses related to prescription opioids—more than the

number of Americans who died in the Vietnam War. From 1999 to 2016, more than 200,000 people died in the U.S. from overdoses related to prescription opioids. Overdose deaths involving prescription opioids were five times higher in 2017 than 1999.

11. As millions became addicted to opioids, "pill mills," often styled as "pain clinics," sprouted nationwide and rogue prescribers stepped in to supply prescriptions for non-medical use. These pill mills, typically under the auspices of licensed medical professionals, issue high volumes of opioid prescriptions under the guise of medical treatment. Prescription opioid pill mills and rogue prescribers cannot channel opioids for illicit use without at least the tacit support and willful blindness of the Defendants, if not their knowing support.

12. As a direct and foreseeable result of Defendants' conduct, cities and counties across the nation, including Plaintiff, are now swept up in what the Centers for Disease Control ("CDC") has called a "public health epidemic" and what the U.S. Surgeon General has deemed an "urgent health crisis."[2] The increased volume of opioid prescribing correlates directly to skyrocketing addiction, overdose and death; black markets for diverted prescriptions opioids; and a concomitant rise in heroin and fentanyl abuse by individuals who could no longer legally acquire or simply could not afford prescription opioids.

13. Thus, rather than compassionately helping patients, this explosion in opioid use and Defendant's profits has come at the expense of patients and has caused ongoing harm and damages to Plaintiff. As the then CDC director concluded: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently.[3]

[2] CDC, *Examining the Growing Problems of Prescription Drug and Heroin Abuse* (Apr. 29, 2014), available at http://www,cdc,give.washington/testimony/2014/t20140429.htm; Vivek H. Murthy, *Letter from the Surgeon General*, August 2016, available at http://turnthetiderx.org.

[3] *Id.*

14. Defendants' conduct distributing opioids and in promoting opioid use, addiction, abuse, overdose and death has had severe and far-reaching public health, social services, and criminal justice consequences, including the fueling of addiction and overdose from illicit drugs such as heroin. The costs are borne by governmental entities. These necessary and costly responses to the opioid crisis include the handling of emergency responses to overdoses, providing addiction treatment, handling opioid-related investigations, arrests, adjudications, and incarceration, treating opioid-addicted newborns in neonatal intensive care units, burying the dead, and placing thousands of children in foster care placements, among others.

15. The burdens imposed on Weymouth are not the normal or typical burdens of government programs and services. Rather, they are extraordinary costs and losses that are related directly to Defendants' illegal actions. The Defendants' conduct has created a public nuisance and blight. Governmental entities, and the services they provide their citizens, have been strained to the breaking point by this public health crisis.

16. Defendants have not changed their ways or corrected their past misconduct but instead are continuing to fuel the crisis.

17. Within the next hour, six Americans will die from opioid overdoses; two babies will be born addicted to opioids and begin to go through withdrawal; and drug manufacturers and distributors will earn millions from the sale of opioids.

18. Weymouth brings this suit to bring the devastating march of this epidemic to a halt and to hold Defendants responsible for the crisis they caused.

II. PARTIES

A. Plaintiff

19. The city known as the Town of Weymouth is located in Norfolk County, Massachusetts. Pursuant to M.G.L. c. 40, §§ 1 and 2, it has the authority to prosecute suits on behalf of the Town.

B. Defendants

20. Purdue Pharma, L.P. ("Purdue") is a limited partnership organized under the laws of Delaware. Purdue Pharma, Inc. is a New York corporation with its principal place of business in Stamford, Connecticut. The Purdue Frederick Company Inc. is a New York corporation with its principal place of business in Stamford, Connecticut. In 2007, Purdue and three of its executives pleaded guilty to federal criminal charges for deceptively marketing opioids.

21. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid and Dilaudid-HP, Butrans, and Hysingla ER in the United States and in Weymuoth.[4] OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between $2 and $3 billion. Nationwide, OxyContin constitutes roughly 25% of the entire market, by spending, for prescription opioids.

22. Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA acquired Cephalon, Inc. in October 2011. Cephalon, Inc. ("Cephalon") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Teva USA and Cephalon work together closely to market and sell Cephalon products in the United States, including Weymouth. Teva USA also sells generic

[4] Purdue also obtained approval to market Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride) in 2014, but it has not actively marketed it.

opioids throughout the United States and Weymouth, including generic opioids previously sold by Allergan plc, whose generics business Teva Pharmaceutical Industries Ltd., Teva USA's parent company based in Israel, acquired in August 2016. These parties are collectively referred to herein as "Teva."

23. Teva manufactures, promotes, sells, and distributes opioids such as Actiq, a fentanyl lollipop, and Fentora, a dissolving pill, throughout the United States and in Weymouth. Actiq and Fentora have been approved by the U.S. Food and Drug Administration ("FDA") only for the "management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain." In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay $425 million.

24. Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Johnson & Johnson ("J&J"), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. Ortho-McNeil-Janssen Pharmaceuticals, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Janssen Pharmaceutica Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. These parties are collectively referred to as "Janssen."

25. J&J imposes a code of conduct on Janssen as a pharmaceutical subsidiary of J&J. The "Every Day Health Care Compliance Code of Conduct" posted on Janssen's website is a J&J company-wide document that describes Janssen as one of the "pharmaceutical Companies of Johnson and Johnson" and as one of the "Johnson & Johnson Pharmaceutical Affiliates." It governs how "[a]ll employees of Johnson & Johnson Pharmaceutical Affiliates," including those of Janssen, "market, sell, promote, research, develop, inform and advertise Johnson & Johnson Pharmaceutical Affiliates' products." All Janssen officers, directors, employees, sales associates must certify that they have "read, understood and will abide by" the code. Thus, the code governs all forms of marketing at issue in this case.

26. In addition, J&J made payments to front groups, discussed herein, who perpetuated and disseminated Defendants' misleading marketing messages regarding the risks and benefits of opioids.[5]

27. Janssen manufactures, promotes, sells, and distributes drugs in the U.S. and Weymouth, including the opioid Duragesic. Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

28. Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals Inc. is a wholly-owned subsidiary of

[5] U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member's Office, Staff Report, *Fueling an Epidemic*, Report Two, *Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, n. 23 ("Payments from Janssen include payments from Johnson & Johnson Health Care Systems, Inc.")

Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. These parties are collectively referred to as "Endo."

29. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the U.S. and in Weymouth. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the U.S. and Weymouth, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc. On July 6, 2017, in response to an FDA request that Endo voluntarily withdraw the product from the market, the company announced that it would stop marketing and selling a reformulated version of Opana ER that it had marketed as abuse-deterrent.

30. Mallinckrodt, plc is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. Mallinckrodt, LLC is a limited liability company organized and existing under the laws of the State of Delaware with its principal place of business in St. Louis, Missouri. Mallinckrodt, LLC is licensed to do business in Massachusetts. Since June 28, 2013, it has been a wholly owned subsidiary of Mallinckrodt, plc. Prior to June 28, 2013 Mallinckrodt, LLC was a wholly-owned subsidiary of Covidien plc. Mallinckrodt Brand Pharmaceuticals is a Delaware Corporation which is wholly owned by Mallinckrodt plc. Defendant SpecGx LLC, Inc. is a Delaware limited liability company with its headquarters in Clayton, Missouri and is a wholly-owned subsidiary of Mallinckrodt plc. SpecGX currently manufactures and sells certain opioids which were

previously manufactured by Mallinckrodt LLC. Mallinckrodt, plc, Mallinckrodt, LLC, Mallinckrodt Brand Pharmaceuticals and SpecGx LLC are referred to as "Mallinckrodt."

31. Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths. In 2009, Mallinckrodt Inc. acquired the U.S. rights to Exalgo. The FDA approved Exalgo for treatment of chronic pain in 2012. Mallinckrodt further expanded its branded opioid portfolio in 2012 by purchasing Roxicodone from Xanodyne Pharmaceuticals. In addition, Mallinckrodt developed Xartemis XR, an extended-release combination of oxycodone and acetaminophen, which the FDA approved in March 2014, and which Mallinckrodt has since discontinued. Mallinckrodt promoted its branded opioid products with its own direct sales force.

32. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. Mallinckrodt estimated that in 2015 it received approximately 25% of the U.S. Drug Enforcement Administration's ("DEA") entire annual quota for the controlled substances that it manufactures.[6] Mallinckrodt also estimated, based on IMS Health data for the same period, that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.

33. Mallinckrodt operates a vertically integrated business in the United States: (1) importing raw opioid materials, (2) manufacturing generic opioid products, primarily at its facility in Hobart, New York, and (3) marketing and selling its products to drug distributors,

[6] https://www.sec.gov/Archives/edgar/data/1567892/000156789216000098/mnk10-k93016.html

specialty pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers that have mail-order pharmacies, and hospital buying groups.

34. Collectively, Purdue, Teva, Janssen, Endo, and Mallinckrodt are referred to herein as "Manufacturing Defendants."

35. The Distributor Defendants are defined below. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Defendants universally failed to comply with federal and/or state law. The Distributor Defendants are engaged in "wholesale distribution," as defined under state and federal law. Weymouth alleges the unlawful conduct by the Distributor Defendants is a substantial cause for the volume of prescription opioids plaguing Weymouth.

36. Cardinal Health, Inc. ("Cardinal") describes itself as a "global, integrated health care services and products company," and is the fifteenth largest company by revenue in the U.S., with annual revenue of $121 billion in 2016. Cardinal distributes pharmaceutical drugs, including opioids, throughout the country, including in Weymouth. Cardinal is an Ohio corporation and is headquartered in Dublin, Ohio. Based on Defendant Cardinal's own estimates, one of every six pharmaceutical products dispensed to United States patients travels through the Cardinal Health network.

37. McKesson Corporation ("McKesson") is fifth on the list of Fortune 500 companies, ranking immediately after Apple and ExxonMobil, with annual revenue of $191 billion in 2016. McKesson is a wholesaler of pharmaceutical drugs that distributes opioids

throughout the country, including in Weymouth. McKesson is incorporated in Delaware, with its principal place of business in San Francisco, California.

38. In January 2017, McKesson paid a record $150 million to resolve an investigation by the U.S. Department of Justice ("DOJ") for failing to report suspicious orders of certain drugs, including opioids. In addition to the monetary penalty, the DOJ required McKesson to suspend sales of controlled substances from distribution centers in Ohio, Florida, Michigan and Colorado. The DOJ described these "staged suspensions" as "among the most severe sanctions ever agreed to by a [Drug Enforcement Administration] registered distributor."

39. AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country, including in Weymouth. It has a distribution center in Mansfield, Massachusetts. AmerisourceBergen is the eleventh largest company by revenue in the United States, with annual revenue of $147 billion in 2016. AmerisourceBergen's principal place of business is located in Chesterbrook, Pennsylvania, and it is incorporated in Delaware.

40. Collectively Cardinal, McKesson and AmerisourceBergen are, at times, referred to herein as "The Big Three."

41. Walgreens Boots Alliance d/b/a Walgreen Co ("Walgreens") includes a captive distributor that supplies pharmaceutical drugs and opioids to Walgreens pharmacies in Weymouth and throughout the country. Walgreens is headquartered in Deerfield, Illinois, and has distribution centers across the country, which distribute medications, including opioids, to various states, including Massachusetts. Walgreens is registered to do business in Massachusetts under the name Walgreens of Massachusetts, LLC.

42. Collectively Cardinal, McKesson, AmerisourceBergen, and Walgreens are at times referred to herein as "Distributor Defendants."

43. The Distributor Defendants dominate the wholesale distribution market, including in Weymouth.

44. For Defendant Jane Does 1 – 50, Weymouth lacks sufficient information to specifically identify the true names or capacities, whether individual, corporate, or otherwise, of these Defendants. Weymouth will amend this Complaint to show their true names when they are ascertained.

III. JURISDICTION AND VENUE

45. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 because the County's claim under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961 *et seq.* ("RICO") raises a federal question. This Court has supplemental jurisdiction over Weymouth's state-law claims under 28 U.S.C. § 1367 because those claims are so related to the RICO claim as to form part of the same case or controversy.

46. Venue is proper in this court pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events and omissions giving rise to the claim occurred in the United States District Court for Massachusetts.

47. This court has personal jurisdiction over Defendants pursuant to M.G.L. c. 223A, § 3 because they transact business in the Commonwealth of Massachusetts, contract to supply goods and manufactured products in the Commonwealth of Massachusetts, carry on a continuous and systematic part of their general businesses within Massachusetts, including in Weymouth, have transacted substantial business with Massachusetts and Weymouth's entities and residents, and have caused grave harm in the Town as a result.

ADDITIONAL ALLEGATIONS COMMON TO ALL COUNTS

48. Until the mid-1990s, opioids were widely thought to be too addictive for use for chronic pain conditions, which would require long-term use of the drugs at increasingly high doses. For these conditions, the risks of addiction and other side effects outweighed any benefit from the drugs. For the last two decades, Manufacturing Defendants have sought to successfully turn that consensus on its head, primarily by covering up the risk of addiction and overstating the benefits of using opioids long-term.

49. Through marketing that was as pervasive as it was deceptive, Manufacturing Defendants convinced health care providers both that the risks of long-term opioid use were overblown and that the benefits, in reduced pain and improved function and quality of life, were proven. Purdue's sales representatives, in particular, promoted the concept that pain was undertreated, that opioids could not be abused, that the rate of addiction to opioids was less than 1%, that "old views" of opioid addiction were untrue, and that "appropriate patients" would not become addicted. These themes were repeated by sales representatives from other Manufacturing Defendants.

50. The result was that by the mid-2000s, the medical community had abandoned its prior caution, and opioids were entrenched as an appropriate—and often the first—treatment for chronic pain conditions. Manufacturing Defendants not only marketed opioids for chronic pain conditions, but also targeted primary care physicians (along with nurse practitioners and physician assistants),[7] who were most likely to see patients with chronic pain conditions and least likely to have the training and experience to evaluate Defendants' marketing claims.

[7] For example, in 2013, Purdue sought to identify Key Opinion Leaders ("KOLs") to reach non-physician prescribers, including for a program to educate nurses about opioids. By 2015, nurse

51. Manufacturing Defendants' deceptive marketing created a cadre of doctors who looked for pain and treated it with opioids, which created an even broader cohort of patients who expected and received opioids. This laid the groundwork for today's epidemic of opioid addiction, injury, and death.

A. Manufacturing Defendants Falsely Trivialized, Mischaracterized, And Failed To Disclose The Known, Serious Risk Of Addiction

52. Manufacturing Defendants rely heavily on their sales representatives to convey their marketing messages and materials to prescribers in targeted, in-person settings. These visits frequently coincide with payments to the prescriber for "promotional speaking," "food and beverage," "consulting," "travel and lodging," "honoraria," and "education." Purdue's former Vice President of Marketing, Russ Gasdia, acknowledged the utility of a Purdue sales representative as "someone [prescribers] can look to for the information they need to make prescribing decisions." Publicly available records show that sales representatives from Purdue, Mallinckrodt and Teva visited and provided some sort of payment to Weymouth prescribers numerous times between the third quarter of 2013 and the end of 2016. However, these numbers understate the amount of "detailing" by these Defendants, as they reflect only visits in which some sort of payment was provided. Upon information and belief, the other Manufacturing Defendants visited Weymouth prescribers in this time period as well. Information regarding each doctor visited and the number of visits is in the hands of the Manufacturing Defendants.

53. The U.S. Senate Homeland Security & Governmental Affairs Committee recently issued a Staff Report which noted the link between drug maker payments to prescribers and

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practitioners and physician assistants were responsible for over 800 million prescriptions and constituted Purdue's largest growth area.

physician prescribing practices. It found that "a clear link exists between even minimal manufacturer payments and physician prescribing practices."[8] The Report quotes ProPublica findings that "doctors who received industry payments were two to three times as likely to prescribe brand-name drugs at exceptionally high rates as others in their specialty."

54. To ensure that sales representatives delivered the desired messages to prescribers, Purdue, Endo, Teva, and Janssen, directed and monitored their respective sales representatives through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and review of representatives' "call notes" from each visit. These Defendants likewise required their sales representatives to use sales aids reviewed, approved, and supplied by the companies and forbade them to use promotional materials not approved by the company's marketing and compliance departments. They further ensured marketing consistency nationwide through national and regional sales representative training. Thus, upon information and belief,[9] their sales forces in Massachusetts and Weymouth carried out national marketing strategies, delivering centrally scripted messages and materials that were consistent across the country.

55. Manufacturing Defendants were aware of the strength of its in-person marketing. The effects of sales calls on prescribers' behavior is well-documented in the literature, including a 2009 study correlating the nearly ten-fold increase in OxyContin prescriptions between 1997 and 2002 to Purdue's doubling of its sales force and trebling its sales calls. A 2017 study found that physicians ordered fewer promoted brand-name medications and prescribed more cost-effective generic versions if they worked in hospitals that instituted rules about when and how

[8] Staff Report, *Fueling an Epidemic, Insys Therapeutics and the Systemic Manipulation of Prior Authorization.*

[9] Unless otherwise noted, allegations based on "information and belief" are based on the uniformity of Defendants' nationwide strategy and practices, which would reasonably be expected to apply in Weymouth in the same manner as elsewhere.

pharmaceutical sales representatives were allowed to detail prescribers. The changes in prescribing behavior appeared strongest at hospitals that implemented the strictest detailing policies and included enforcement measures. Another study involved the research of four different practices which included visits by sales representatives, medical journal advertisements, direct-to-consumer advertising, and pricing, and found that sales representatives have the strongest effect on driving drug utilization. An additional study found that doctor meetings with sales representatives are related to changes in doctor prescribing practices and requests by physicians to add the drugs to hospitals' formularies.

56. Manufacturing Defendants also used "key opinion leaders" ("KOLs")—experts in the field who were especially influential because of their reputations and seeming objectivity—to deliver paid talks and continuing medical education programs (or "CMEs") that provided information about treating pain and the risks, benefits, and use of opioids. These KOLs received substantial funding and research grants from these Defendants, and the CMEs were often sponsored by Manufacturing Defendants—giving them considerable influence over the messenger, the message, and the distribution of the program. Only doctors supportive of the use and safety of opioids for chronic pain received these funding and speaking opportunities, which were not only lucrative, but helped doctors build their reputations and bodies of work. One leading KOL, Dr. Russell Portenoy, subsequently acknowledged that he gave lectures on opioids that reflected "misinformation" and were "clearly the wrong thing to do."

57. In addition to talks and CMEs, these KOLs served on the boards of patient advocacy groups and professional associations, such as the American Pain Foundation and the American Pain Society, that were also able to exert greater influence because of their seeming independence. Manufacturing Defendants exerted influence over these groups by providing

major funding directly to them, as well. These "front groups" for the opioid industry put out patient education materials and treatment guidelines that supported the use of opioids for chronic pain, overstated their benefits, and understated their risks. In many instances, Manufacturing Defendants distributed these publications to prescribers or posted them on their websites.

1. Minimizing or mischaracterizing the risk of addiction

58. To convince prescribers and patients that opioids are safe, Manufacturing Defendants deceptively represented that the risk of abuse and addiction is modest and manageable and limited to illegitimate patients, not those with genuine pain. This created the dangerously misleading impressions that: (1) patients receiving opioid prescriptions for chronic pain would not become addicted: (2) patients at greatest risk of addiction could be identified; (3) all other patients could safely be prescribed opioids; and (4) even high risk patients could be prescribed opioids if closely managed.

59. Upon information and belief, sales representatives regularly omitted from their sales conversations with prescribers in Weymouth any discussion of the risk of addiction from long-term use of opioids. These omissions rendered other arguably truthful statements about opioids false and misleading, and they both reinforced and failed to correct their prior misrepresentations regarding the risk of addiction.

60. Manufacturing Defendants also deceptively undermined evidence that opioids are addictive by suggesting or stating that the risk of addiction is limited to specific, high-risk patients. According to these Defendants, doctors can screen patients to identify those who are likely to become addicted, and therefore could safely prescribe to everyone else. Manufacturing Defendants discounted general concerns or warnings regarding addiction by reassuring doctors that their patients would not become addicted. One former Purdue sales representative in another region confirmed Purdue's message that opioids were appropriate and safely prescribed

to legitimate patients with actual pain; upon information and belief, based on the uniformity of Purdue's practices, the same message was delivered to prescribers in Weymouth. These assurances were false and unsafe, as prescribers cannot accurately predict which patients are at higher risk of addiction. In addition, upon information and belief, Manufacturing Defendants' sales representatives also failed to disclose to prescribers in Weymouth the difficulty of withdrawing from opioids. Discontinuing or delaying opioids can cause intense physical and psychological effects, including anxiety, nausea, headaches, and delirium, among others. This difficulty in terminating use is a material risk, which can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

61. Manufacturing Defendants falsely portrayed "true" addiction in its narrowest form. *Providing Relief, Preventing Abuse*, a pamphlet published by Purdue in 2011 for prescribers and law enforcement, shows pictures of the signs of injecting or snorting opioids—skin popping, track marks, and perforated nasal septa—under the heading "Indications of Possible Drug Abuse." Purdue knew that opioid addicts who resort to these extremes are uncommon; they far more typically become dependent and addicted through oral use. According to briefing materials Purdue submitted to the FDA in October 2010, OxyContin was used non-medically by injection as little as 4% of the time.

62. These depictions misleadingly reassured doctors that, in the absence of those extreme signs, they need not worry that their patients are abusing or addicted to opioids. Purdue made *Providing Relief, Preventing Abuse* available to sales representatives to show to or leave with prescribers, including, on information and belief, to prescribers in Weymouth.

63. Purdue also disseminated misleading information about opioids and addiction through the American Pain Foundation ("APF"). Purdue was APF's second-biggest donor.

Purdue grant letters informed APF that Purdue's contributions reflected the company's effort to "strategically align its investments in nonprofit organizations that share [its] business interests." Purdue also engaged APF as a paid consultant on various initiatives and deployed APF to lobby for its interests on Capitol Hill.

64. *A Policymaker's Guide to Understanding Pain & Its Management*, a 2011 APF publication that Purdue sponsored, claimed that pain generally had been "undertreated" due to "[m]isconceptions about opioid addiction." This guide also asserted, without basis, that "less than 1% of children treated with opioids become addicted" and perpetuated the concept of pseudoaddiction. Purdue provided substantial funding in the form of a $26,000 grant to APF and closely collaborated with APF in creating *A Policymaker's Guide.* On information and belief, based on Purdue's close relationship with APF and the periodic reports APF provided to Purdue about the project, Purdue had editorial input into *A Policymaker's Guide*.

65. Purdue also maintained a website from 2008 to 2015, *In the Face of Pain* that downplayed the risks of chronic opioid therapy. Purdue deactivated this website in October 2015 following an investigation by the New York Attorney General. Although it included the Purdue copyright at the bottom of each page, the site did not refer to any specific Purdue products and cultivated the "impression that it [was] neutral and unbiased."[10]

66. *In the Face of Pain* asserted that policies limiting access to opioids are "at odds with best medical practices" and encouraged patients to be "persistent" in finding doctors who will treat their pain. While a document linked from the website briefly mentioned opioid abuse, the site itself *never* mentioned the risk of addiction. At the same time, the website contained

[10] Attorney General of the State of New York, *In the Matter of Purdue Pharma L.P.*, Assurance No.: 15-151 (August 19, 2015).

testimonials from several dozen physician "advocates" speaking positively about opioids. Eleven of these advocates received a total of $231,000 in payments from Purdue from 2008 to 2013—a fact notably omitted from the site.

67. Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

68. Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website www.opana.com.

69. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain." This guide is still available online.

70. Janssen currently runs a website, *Prescriberesponsibly.com*, which claims that concerns about opioid addiction are "overestimated."

71. Until at least June 2007, Mallinckrodt gave education grants to pain-topics.org, a now defunct website that proclaimed to be an organization "dedicated to offering contents that are evidence-based, unbiased, non-commercial, and comply with the highest standards and

principles of accrediting and other oversight organizations."[11]

72. The FAQs section of pain-topics.org contained misleading information about pseudoaddiction, discussed further in subsection 2. Specifically, the website described pseudoaddiction as behavior that occurs in patients when pain is "undertreated" and includes patients becoming "very focused on obtaining opioid medications and may be erroneously perceived as 'drug seeking.'"[12]

73. Among its content, the website contained a handout titled *Oxycodone Safety for Patients,* which advised doctors that "[p]atients' fears of opioid addiction should be expelled."[13] The handout stated the following misleading information regarding the risk of addiction:

Will you become dependent on or addicted to oxycodone?

- After awhile, oxycodone causes *physical dependence*. That is, if you suddenly stop the medication you may experience uncomfortable withdrawal symptoms, such as diarrhea, body aches, weakness, restlessness, anxiety, loss of appetite, and other ill feelings. These may take several days to develop.
- This is not the same as *addiction*, a disease involving craving for the drug, loss of control over taking it or compulsive use, and using it despite harm. Addiction to oxycodone in persons without a recent history of alcohol or drug problems is rare.

This handout is still available to prescribers and patients today.

74. In 2010, according to a Mallinckrodt Policy Statement, Mallinckrodt launched the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which it describes as "a coalition of national patient safety, provider and drug diversion organizations that are

[11] https://web.archive.org/web/20070701065905/http://www.pain-topics.org:80/contacts_aboutus/index.php, (Last visited March 2, 2018.)

[12] https://web.archive.org/web/20071026152321/http://pain-topics.org/faqs/index1.php#tolerance (Last visited March 2, 2018.)

[13] Lee A. Kral, *Commonsense Oxycodone Prescribing & Safety*, http://paincommunity.org/blog/wp-content/uploads/OxycodoneHandout.pdf.

focused on reducing opioid pain medication abuse and increasing responsible prescribing habits." Mallinckrodt further states: "Through the C.A.R.E.S. Alliance website, prescribers and pharmacists can access tools and resources to assist them in managing the risks of opioid pain medications, and patients can find information designed to help them better manage their pain and understand the responsible use of the medications they take." By 2012, the C.A.R.E.S. Alliance and Mallinckrodt were promoting a book titled *Defeat Chronic Pain Now!* The false claims and misrepresentations in this book include the following statements:

a. "Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."

b. "[O]pioid medication may also significantly relieve many patients' chronic pain. Over the past decade, lots of good scientific studies have shown that long-acting opioids can reduce the pain in some patients with low back pain, neuropathic pain, and arthritis pain."

c. "It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy."

d. "[P]hysical dependence ... is a normal bodily reaction that happens with lots of different types of medications, including medications not used for pain, and is easily remedied."

e. "When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving."

f. "[I]n our experience, the issue of tolerance is overblown."

g. "Only a minority of chronic pain patients who are taking long-term opioids develop tolerance."

h. "**The bottom line:** Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."

i. "Here are the facts. It is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."

j. "Studies have shown that many chronic pain patients can experience significant

> pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction."

This book is still available online in Weymouth and elsewhere.

75. Neither these third-party unbranded materials, nor the marketing messages or scripts relied on by Manufacturing Defendants' sales representatives, were reviewed or approved by the U.S. Food & Drug Administration ("FDA"). Upon information and belief, all of the messages described below were disseminated to Weymouth prescribers and patients through sales representative visits, medical education programs, marketing materials, websites, and other sources.

76. Manufacturing Defendants' efforts to trivialize the risk of addiction were, and remain, at odds with the scientific evidence. Studies have shown that at least 8-12%, and as many as 30-40% of long-term users of opioids experience problems with addiction. In March 2016, the FDA emphasized the "known serious risk[] of ... addiction"—"even at recommended doses"—of all opioids."[14] That same month, after a "systematic review of the best available evidence" by a panel excluding experts with conflicts of interest, the CDC published the CDC Guideline for prescribing opioids for chronic pain. The CDC Guideline noted that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" (a diagnostic term for addiction).[15] The CDC also emphasized that "continuing opioid therapy for 3 months

[14] *FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics,* FDA (Sep. 10, 2013); *see also FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death,* FDA (Mar. 22, 2016), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm.

[15] CDC Guideline at 2.

substantially increases risk for opioid use disorder."[16] An additional study showed that nearly 60% of patients who used opioids for 90 days continued to use opioids five years later.

2. Manufacturing Defendants Falsely Described Addiction as Pseudoaddiction and Dangerously Encouraged Doctors to Respond by Prescribing More Opioids

77. Manufacturing Defendants deceptively advised doctors to ignore signs of addiction as the product of an unfounded condition it called pseudoaddiction. Pseudoaddiction was a concept invented to foster the misconception that signs of addiction, including shopping for doctors willing to newly write or refill prescriptions for opioids or seeking early refills, actually reflected undertreated pain that should be addressed with more opioids—the medical equivalent of fighting fire by adding fuel.

78. Purdue, through its unbranded imprint *Partners Against Pain*,[17] promoted pseudoaddiction through at least 2013 on its website.

79. The Federation of State Medical Boards ("FSMB"), a trade organization representing Massachusetts state medical board as well as others, finances opioid- and pain-specific programs through grants from Manufacturing Defendants. A 2004 version of the FSMB *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("FSMB Guidelines"), and the 2007 book adapted from them, *Responsible Opioid Prescribing*, advanced the concept of "pseudoaddiction."

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[16] *Id.* at 21.

[17] *Partners Against Pain* consists of both a website, styled as an "advocacy community" for better pain care, and medical education resources distributed to prescribers by the sales force. It has existed since at least the early 2000s and has been a vehicle for Purdue to downplay the risks of addiction from long-term opioid use. One early pamphlet, for example, answered concerns about OxyContin's addictiveness by claiming: "Drug addiction means using a drug to get 'high' rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful."

80. *Responsible Opioid Prescribing* was sponsored by Manufacturing Defendants. The FSMB website described the book as the "leading continuing medical education (CME) activity for prescribers of opioid medications." In all, more than 163,000 copies of *Responsible Opioid Prescribing* were distributed nationally, including, upon information and belief, in Weymouth.

81. Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "pseudoaddiction ... refers to patient behaviors that may occur when *pain is under-treated* ... . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management." This website was accessible online until May 2012.

82. Endo sponsored a National Initiative on Pain Control ("NIPC") CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.

83. Manufacturing Defendants also promoted the concept of pseudoaddiction through Dr. Russell Portenoy, a leading KOL for the Manufacturing Defendants. In doing so, he popularized the concept and falsely claimed that pseudoaddiction is substantiated by scientific evidence.

84. The CDC Guideline rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid doses be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment ... are unlikely to experience pain relief with longer-

term use,"[18] and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."[19]

3. Overstating the efficacy of screening tools

85. Manufacturing Defendants falsely instructed prescribers and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow health care providers to safely prescribe opioids to patients, including patients predisposed to addiction, and failed to disclose the lack of evidence that these strategies will mitigate addiction risk. By using screening tools, these Defendants, advised that doctors could identify those who are likely to become addicted and could safely prescribe to everyone else. Thus, Manufacturing Defendants undermined general concerns or warnings regarding addiction by reassuring doctors that, despite the general warnings about addiction, their patients would not become addicted.

86. Such misrepresentations regarding safe opioid prescribing made health care providers more comfortable prescribing opioids to their patients, and patients more comfortable starting chronic opioid therapy. These misrepresentations were especially insidious because Purdue aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Moreover, these misrepresentations reassured doctors that opioid addiction was the result of other prescribers failing to rigorously manage and weed out problem patients.

87. Upon information and belief, these Defendants conveyed these safe prescribing messages through their in-person sales calls to doctors in Weymouth.

[18] CDC Guideline at 13.

[19] *Id.* at 25.

88. On information and belief, based on their use elsewhere, Purdue sales representatives in Weymouth also shared the *Partners Against Pain* "Pain Management Kit," which contained several "drug abuse screening tools." These included the "Opioid Risk Tool," which is a five question, one-minute screening tool that relies on patient self-reporting to identify whether there is a personal history of substance abuse, sexual abuse, or "psychological disease," ignoring the sensitivity of the topic and the nature of addiction, which make it unlikely that many patients can be counted on to share this information.

89. Manufacturing Defendants also promoted screening tools as a reliable means to manage addiction risk in CME programs and scientific conferences, which likely were attended by and were available to Weymouth prescribers.

90. For example, Purdue sponsored a 2011 CME program titled *Managing Patients' Opioid Use: Balancing the Need and Risk*. This presentation deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented "overuse of prescriptions" and "overdose deaths."

91. Purdue also funded a 2012 CME program called *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*. The presentation deceptively instructed doctors that, through the use of screening tools, more frequent refills, and other techniques, high-risk patients showing signs of addictive behavior could be treated with opioids.

92. Purdue used its involvement in the College on the Problems of Drug Dependence ("CPDD"), which promotes scientific research and professional development to support addiction prevention professionals, to promote the idea that addiction risk can be managed. A Purdue employee served on the CPDD board of directors. Purdue presented an outsized number

of talks—with very different messages from non-Purdue talks—at each CPDD conference. One of Purdue's consistent themes is that "bad apple" patients, not opioids, are the source of the addiction crisis, and that once those patients are identified doctors can safely prescribe opioids without addicting patients. Hundreds of addiction treatment specialists from across the country and, upon information and belief, prescribers from Weymouth, attended these conferences.

93. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo's speakers' bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

94. A 2011 non-credit educational program sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms, which make it difficult for patients to stop using opioids, can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days.

95. Manufacturing Defendants' efforts to convince doctors that they could confidently prescribe to pain patients who did not intend to become addicted or abuse drugs were misleading. As these Defendants knew or should have known, sales to patients who doctor-shop (or visit multiple doctors to hide illicit use or overuse) constitute approximately only 1% of opioid volume.

96. Further, the CDC Guideline confirms the falsity of Manufacturing Defendants' claims about the utility of patient screening and management strategies in managing addiction risk. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation

strategies—such as screening tools or patient contracts—"for improving outcomes related to overdose, addiction, abuse, or misuse." The CDC Guideline recognizes that available risk screening tools "show *insufficient accuracy* for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."[20]

B. Manufacturing Defendants Overstated the Benefits of Chronic Opioid Therapy While Failing to Disclose the Lack of Evidence Supporting Long-Term Use

1. Mischaracterizing the benefits and evidence for long-term use

97. To convince prescribers and patients that opioids should be used to treat chronic pain, Manufacturing Defendants had to persuade them of a significant upside to long-term opioid use. Assessing existing evidence, the CDC Guideline found that there is "*insufficient evidence* to determine the long-term benefits of opioid therapy for chronic pain."[21] In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)"[22] and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks."[23] The FDA also determined that opioid use disorder and overdose risk are present when opioids are taken as prescribed. As a result, the CDC recommends that opioids be used not in the first instance and

[20] CDC Guideline at 28 (emphasis added).

[21] *Id.* at 10.

[22] *Id.* at 9.

[23] Letter from Janet Woodcock, M.D, Dir., Center for Drug Eval. and Research, to Andrew Kolodny, M.D. (Sept. 10, 2013).

only after prescribers have exhausted alternative treatments.

98. Upon information and belief, Manufacturing Defendants touted the purported benefits of long-term opioid use, while falsely and misleadingly suggesting that these benefits were supported by scientific evidence.

99. Two prominent professional medical membership organizations, the American Pain Society ("APS") and the American Academy of Pain Medicine ("AAPM"), each received substantial funding from Manufacturing Defendants. Upon information and belief, Manufacturing Defendants exercised considerable influence over their work on opioids. Both organizations issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. David Haddox, was at the time a paid speaker for Purdue and later became a senior executive for the company. KOL Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011. The statement was taken down from AAPM's website only after a doctor complained.

100. AAPM and APS issued treatment guidelines in 2009 ("AAPM/APS Guidelines") which continued to recommend the use of opioids to treat chronic pain. Treatment guidelines, like the AAPM/APS Guidelines, were particularly important to Manufacturing Defendants in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain. Six of the twenty-one panel members who drafted the AAPM/APS Guidelines received support from Purdue, eight from Teva, nine from Janssen, and ten from Endo.

101. The AAPM/APS Guidelines promote opioids as "safe and effective" for treating

chronic pain. The panel made "strong recommendations" despite "low quality of evidence" and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the Guidelines were influenced by contributions that drug companies, including Purdue, Endo, Janssen, and Teva made to the sponsoring organizations and committee members.

102. Dr. Gilbert Fanciullo, a retired professor at Dartmouth College's Geisel School of Medicine who served on the AAPM/APS Guidelines panel, has since described them as "skewed" by drug companies and "biased in many important respects," including its high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

103. The AAPM/APS Guidelines are still available online, were reprinted in the *Journal of Pain*, and have influenced not only treating physicians, but also the body of scientific evidence on opioids. According to Google Scholar, they have now been cited at least 1,647 times in academic literature.

104. Manufacturing Defendants also published misleading studies to enhance the perception that opioids are effective long-term for chronic pain conditions. One study asserts that OxyContin is safe and effective for the chronic pain condition osteoarthritis. The study, sponsored by Purdue, involved providing oxycodone for 30 days, and then randomizing participants and providing a placebo, IR oxycodone with acetaminophen (like Percocet), or OxyContin. Only 107 of the 167 patients went on to the second phase of the study, and most who withdrew left because of adverse events (nausea, vomiting, drowsiness, dizziness, or

headache) or ineffective treatment. Despite relating to a chronic condition, opioids were provided only short-term. The authors even acknowledge that the "results… should be confirmed in trials of longer duration to confirm the role of opioids in a chronic condition such as OA [osteoarthritis]."[24] Yet, the authors conclude that "[t]his clinical experience shows that opioids were well tolerated with only rare incidence of addiction and that tolerance to the analgesic effects was not a clinically significant problem when managing patients with opioids long-term."[25] This statement is not supported by the data—a substantial number of patients dropped out because of adverse effects, there was no reported data regarding addiction, and the study was not long-term.

105. Teva deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid-tolerant individuals.

106. Both Actiq and Fentora are extremely powerful fentanyl-based opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Teva from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse—which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.

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[24] Jacques R. Caldwell, *et al.*, *Treatment of Osteoarthritis Pain with Controlled Release Oxycodone or Fixed Combination Oxycodone Plus Acetaminophen Added to Nonsteroidal Antiinflammatory Drugs: A Double Blind, Randomized, Multicenter, Placebo Controlled Trial*, 266.4 JOURNAL OF RHEUMATOLOGY 862-869 (1999).

[25] *Id.*

107. Despite this, Teva conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. As part of this campaign, Teva used CMEs, speaker programs, KOLs, journal supplements, and detailing[26] by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain, without disclosing the lack of evidence or the FDA's rejection of their use for chronic pain.

108. For example: Teva paid to have a CME it sponsored, Opioid-Based Management of Persistent and Breakthrough Pain, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

109. Teva's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.

110. In December 2011, Teva widely disseminated a journal supplement entitled "*Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)*" to Anesthesiology News, Clinical Oncology News, and Pain Medicine News—three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain," and not just cancer pain.

111. Teva's deceptive marketing gave doctors and patients the false impression that

[26] Pharmaceutical detailing is a one-on-one marketing technique utilized by pharmaceutical companies to educate a physician about a vendor's products in hopes that the physician will prescribe the company's products more often.

Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

112. In December 28, 2011, the FDA mandated a Risk Evaluation and Mitigation Strategy ("REMS") for the class of products for which Teva's Actiq and Fentora belong, Transmucosal Immediate Release Fentanyl ("TIRF"). The TIRF REMS programs include mandatory patient and prescriber enrollment forms, as well as certification requirements for prescribers. The forms are not totally comprehensive and do not, for instance, disclose that addiction can develop when prescribed as directed, nor do they disclose that risks are greatest at higher doses—and patients must already be taking high doses of opioids to be prescribed Actiq and Fentora.

2. Overstating opioids' effect on patients' function and quality of life

113. Upon information and belief, Manufacturing Defendants also claimed to Weymouth doctors—without evidence—that long-term opioid use would help patients resume their lives and jobs.

114. Manufacturing Defendants' and Defendant-sponsored materials that, upon information and belief, were distributed or made available in Weymouth, reinforced this message. The 2011 publication *A Policymaker's Guide* falsely claimed that "multiple clinical studies have shown that opioids are effective in improving daily function and quality of life for chronic pain patients." A series of medical journal advertisements for OxyContin in 2012 presented "Pain Vignettes"—case studies featuring patients with pain conditions persisting over several months—that implied functional improvement. For example, one advertisement described a "writer with osteoarthritis of the hands" and implied that OxyContin would help him work more effectively.

115. Similarly, since at least May 21, 2011, Endo has distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker and chef, misleadingly implying that the drug would provide long-term pain-relief and functional improvement.

116. Defendant Mallinckrodt's website, in a section on "responsible use" of opioids, claims that "[t]he effective pain management offered by medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society."[27] Additional illustrative examples are described below:

a. Janssen sponsored and edited a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009)—which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs and states that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'"

b. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function.

c. Responsible Opioid Prescribing (2007), sponsored and distributed by Teva, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.

d. Purdue and Teva sponsored APF's Treatment Options: *A Guide for People Living with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve." The guide was available online until APF shut its doors in May 2012.

e. Endo's NIPC website painknowledge.com claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted

[27] Mallinckrodt Pharmaceuticals, *Responsible Use*, www.mallinckrodt.com/corporate-responsibility/responsible-use.

improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.

f. Endo was the sole sponsor, through NIPC, of a series of CMEs titled Persistent Pain in the Older Patient, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.

117. Likewise, Manufacturing Defendants' claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. As noted above, there are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients' pain and function long-term. On the contrary, the available evidence indicates opioids are not effective to treat chronic pain, and may worsen patients' health and pain. Increasing the duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization.

118. One pain specialist observed, "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."[28] Studies of patients with lower back pain and migraine headaches, for example, have consistently shown that patients experienced deteriorating function over time, as measured by ability to return to work, physical activity, pain

[28] Andrea Rubinstein, *Are We Making Pain Patients Worse?*, SONOMA MED. (Fall 2009), http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse?

relief, rates of depression, and subjective quality-of-life measures. Analyses of workers' compensation claims have found that workers who take opioids are almost four times more likely to reach costs over $100,000, stemming from greater side effects and slower returns to work. According to these studies, receiving an opioid for more than seven days also increased patients' risk of being on work disability one year later.

119. The CDC Guideline notes that "there is no good evidence that opioids improve pain or function with long-term use."[29] The FDA and other federal agencies have made this clear for years. [30] The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations."[31] The CDC Guideline concluded that "[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant."[32] According to the CDC, "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[33]

120. In materials Manufacturing Defendants produced, sponsored, or controlled, Manufacturing Defendants omitted known risks of chronic opioid therapy and emphasized or

[29] *Id.* at 20.

[30] The FDA has warned other drug makers that claims of improved function and quality of life were misleading. *See e.g., Warning Letter from Thomas Abrams*, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), (rejecting claims that Actavis' opioid, Kadian, had an "overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."); *Warning Letter from Thomas Abrams*, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008), (finding the claim that "patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."). The FDA's warning letters were available to Defendants on the FDA website.

[31] CDC Guideline at 2.

[32] *Id* at 18.

[33] *See* n. 23, *supra*.

exaggerated risks of competing products so that prescribers and patients would be more likely to choose opioids and would favor opioids over other therapies such as over-the-counter acetaminophen or nonsteroidal anti-inflammatory drugs (or NSAIDs, like ibuprofen). None of these claims were corroborated by scientific evidence.

3. Omitting or mischaracterizing adverse effects of opioids

121. In addition to failing to disclose in promotional materials the risks of addiction, abuse, overdose, and respiratory depression, Manufacturing Defendants routinely ignored the risks of hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy,"[34] in which the patient becomes more sensitive to pain over time, hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome (when an infant exposed to opioids prenatally withdraws from the drugs after birth); and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety (often among veterans, for example, post-traumatic stress disorder and anxiety also can accompany chronic pain symptoms).

122. Purdue and Teva sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication inaccurately attributes 10,000 to 20,000 deaths annually to NSAIDs (the actual figure is approximately 3,200, far fewer than from opioids).[35] This publication also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning

[34] *See* n. 233, *supra*.

[35] The higher figure reflects deaths from all causes.

about opioids.

123. Purdue also sponsored APF's *Exit Wounds* (2009), a book aimed at veterans. This book omits warnings of the potentially fatal risk of interactions between opioids and benzodiazepines, a class of drug commonly prescribed to veterans with post-traumatic stress disorder. This book is available from Amazon.com and other retailers.

124. Purdue sponsored a CME program, *Overview of Management Options*, published by the American Medical Association in 2003, 2007, 2010, and 2013, and discussed further below. The CME was edited by Dr. Russell Portenoy, among others, and taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

125. Manufacturing Defendants frequently contrasted the lack of a ceiling dosage for opioids with the risks of a competing class of analgesics: over-the-counter nonsteroidal anti-inflammatories (or NSAIDs). These Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from opioids. (*See e.g.*, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (Endo) (describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids); *Finding Relief: Pain Management for Older Adults* (Janssen) (NSAIDs caused kidney or liver damage and increased risk of heart attack and stroke, versus opioids, which cause temporary "upset stomach or sleepiness" and constipation)).

126. These omissions are significant and material to patients and prescribers. A Cochrane Collaboration review of evidence relating to the use of opioids for chronic pain found that 22% of patients in opioid trials dropped out before the study began because of the "intolerable effects" of opioids.[36]

[36] Meredith Noble M, *et al*., *Long- Term Opioid Management for Chronic Noncancer Pain (Review)*, COCHRANE DATABASE OF SYSTEMATIC REVIEWS, Issue 1, 11 (2010.).

127. Again, Manufacturing Defendants' misrepresentations were effective. A study of 7.8 million doctor visits nationwide between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits while NSAID and acetaminophen prescriptions fell from 38% to 29%. The CDC reports that the quantity of opioids dispensed per capita trebled from 1999 to 2015.

C. Manufacturing Defendants Continued to Tell Doctors that Opioids Could Be Taken in Ever Higher Doses Without Disclosing Their Greater Risks

128. Manufacturing Defendants falsely claimed to prescribers and consumers that opioids could be taken in ever-increasing strengths to obtain pain relief, without disclosing that higher doses increased the risk of addiction and overdose. This was particularly important because patients on opioids for more than a brief period develop tolerance, requiring increasingly high doses to achieve pain relief. These Defendants needed to generate a comfort level among doctors to prescribe higher doses, rather than prescribe OxyContin more frequently than twice a day, despite knowing that OxyContin frequently did not provide 12 hours of relief to ensure the doctors maintained patients on the drugs even at the high doses that became necessary.

129. Purdue-sponsored publications and CMEs available, upon information and belief, in Weymouth also misleadingly suggested that higher opioid doses carried no added risk.

130. Through at least June 2015, Purdue's *In the Face of Pain* website promoted the notion that if a patient's doctor did not prescribe a sufficient dose of opioids, the patient should see different doctors until finding a doctor who would.

131. *A Policymaker's Guide*, the 2011 publication on which, upon information and belief Purdue collaborated with APF, taught that dose escalations are "sometimes necessary," but did not disclose the risks from high dose opioids.

132. The Purdue-sponsored CME, *Overview of Management Options*, discussed above, again instructed physicians that NSAIDs (like ibuprofen) are unsafe at high doses (because of risks to patients' kidneys), but did not disclose risks from opioids at high doses. Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."

133. Endo distributed a pamphlet edited by Dr. Russell Portenoy entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was still available after May 21, 2011 on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. ... You won't 'run out' of pain relief."

134. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages. This guide is still available online.

135. These claims conflict with the scientific evidence. Patients receiving high doses of opioids (*e.g.*, doses greater than 100 mg morphine equivalent dose ("MED") per day) as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to opioids' analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended. The CDC Guideline concludes that the "[b]enefits of high-dose opioids for chronic pain are not established" while "there is an increased risk for serious

harms related to long-term opioid therapy that appears to be dose-dependent."[37] That is why the CDC advises doctors to "avoid increasing doses" above 90 mg MED.[38]

D. Purdue Misleadingly Promoted OxyContin as Supplying 12 Hours of Pain Relief When Purdue Knew That, For Many Patients, It did Not

136. To convince prescribers and patients to use OxyContin, Purdue misleadingly promoted the drug as providing 12 continuous hours of pain relief with each dose. In reality, OxyContin does not last for 12 hours in many patients, a fact Purdue has known since the product's launch.

137. These misrepresentations, which Purdue continues to make, are particularly dangerous because inadequate dosing helps fuel addiction, as explained below. Purdue conveyed to prescribers that the solution to end of dose failure is not more frequent dosing but higher doses—which pose greater risks.

138. OxyContin has been FDA-approved for twice-daily—"Q12"—dosing frequency since its debut in 1996. Yet it was Purdue's decision to submit OxyContin for approval with 12-hour rather than 8-hour dosing.

139. Under FDA guidelines for establishing dosing, Purdue merely had to show that OxyContin lasted for 12 hours for at least half of patients, and Purdue submitted a single study that cleared that bar. While the OxyContin label indicates that "[t]here are no well-controlled clinical studies evaluating the safety and efficacy with dosing more frequently than every 12 hours," Purdue has conducted no such studies.

[37] CDC Guideline at 19. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged, "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality."

[38] CDC Guideline at 16.

140. From the outset, Purdue leveraged 12-hour dosing to promote OxyContin as providing continuous, round-the-clock pain relief with the convenience of not having to wake to take a third or fourth pill. The 1996 press release for OxyContin touted 12-hour dosing as providing "smooth and sustained pain control all day and all night." But the FDA has never approved such a marketing claim. To the contrary, the FDA found in 2008, in response to a Citizen Petition by the Connecticut Attorney General, that a "substantial number" of chronic pain patients taking OxyContin experienced "end of dose failure"—*i.e.*, little or no pain relief at the end of the dosing period.

141. Moreover, Purdue itself long has known, dating to its development of OxyContin, that the drug wears off well short of 12 hours in many patients. In one early Purdue clinical trial, a third of patients dropped out because the treatment was ineffective. Researchers changed the rules to allow patients to take supplemental painkillers—"rescue medication"—in between OxyContin doses. In another study, most patients used rescue medication, and 95% resorted to it at least once. In other research conducted by Purdue, the drug wore off in under 6 hours in 25% of patients and in under 10 hours in more than 50%.

142. End-of-dose failure renders OxyContin even more dangerous because patients begin to experience distressing psychological and physical withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin's 12-hour dosing "the perfect recipe for addiction."[39] Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a

[39] Harriet Ryan, "*'You Want a Description of Hell?' OxyContin's 12-Hour Problem*," LOS ANGELES TIMES, May 5, 2016, http://www.latimes.com/projects/oxycontin-part1/.

rescue dose of another opioid, increasing the overall amount of opioids they are taking.

143. Purdue has remained committed to 12-hour dosing because it is key to OxyContin's market dominance and comparatively high price; without this advantage, the drug had little to offer over less expensive, short-acting opioids. In a 2004 letter to the FDA, Purdue acknowledged that it had not pursued approval to allow more frequent dosing in the label (*e.g.*, every 8 hours) because 12-hour dosing was "a significant competitive advantage." Purdue also falsely promoted OxyContin as providing "steady state" relief, less likely than other opioids to create a cycle of crash and cravings that fueled addiction and abuse—a misrepresentation made upon information and belief, in Weymouth.

144. Without appropriate caveats, promotion of 12-hour dosing by itself is misleading because it implies that the pain relief supplied by each dose lasts 12 hours, which Purdue knew to be untrue for many, if not most, patients. FDA approval of OxyContin for 12-hour dosing does not give Purdue license to misrepresent the duration of pain relief it provides to patients; moreover, Purdue had a responsibility to correct its label to reflect appropriate dosing, to disclose to prescribers what it knew about OxyContin's actual duration, and not to promote more dangerous higher dosing, rather than increased frequency of use, regardless of any marketing advantage.

145. Purdue was also aware of some physicians' practice of prescribing OxyContin more frequently than 12 hours—a common occurrence. Purdue's promoted solution to this problem was to increase the dose, rather than the frequency, of prescriptions, even though higher dosing carries its own risks—including increased danger of addiction, overdose, and death. It means that patients will experience higher highs and lower lows, increasing their craving for their next pill. Nationwide, based on an analysis by the LOS ANGELES TIMES, more than 52% of

patients taking OxyContin longer than three months are on doses greater than 60 milligrams per day—which converts to the 90 milligrams of morphine equivalent that the CDC Guideline urges prescribers to "avoid" or "carefully justify."[40]

E. Purdue and Endo Overstated the Efficacy of Abuse-Deterrent Opioid Formulations

146. Rather than take the widespread abuse and addiction to opioids as reason to cease their untruthful marketing claims and efforts, Defendants Purdue and Endo seized them as a market opportunity. These companies oversold their abuse-deterrent formulations ("ADF") as a solution to opioid abuse and as a reason that doctors could continue to safely prescribe their opioids. Purdue's and Endo's false and misleading marketing of the benefits of its ADF opioids preserved and expanded its sales and enabled prescribers to discount evidence of opioid addiction and abuse and attribute it to other, less safe opioids—and thereby prolonged the opioid epidemic in Weymouth.

1. Purdue's deceptive marketing of reformulated OxyContin and Hysingla ER

147. Reformulated, ADF OxyContin was approved by the FDA in April 2010. However, the FDA noted that "the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)." It was not until 2013 that the FDA, in response to a Citizen Petition filed by Purdue, permitted reference to the abuse-deterrent properties in the label. When Hysingla ER (extended-release hydrocodone) launched in 2014, the product included similar abuse-deterrent properties.

148. It is unlikely to be a coincidence that reformulated OxyContin was introduced shortly before generic versions of OxyContin were to become available, threatening to erode

[40] CDC Guideline at 16.

Purdue's market share and the price it could charge. Through a Citizen Petition, Purdue was able to secure a determination by the FDA in April 2013 that original OxyContin should be removed from the market as unsafe (lacking abuse-deterrent properties), and thus non-ADF generic copies could not be sold. As a result, Purdue extended its branded exclusivity for OxyContin until the patent protection on the abuse-deterrent coating expires.

149. Upon information and belief, Purdue nonetheless touted its introduction of ADF opioids as evidence of its good corporate citizenship and commitment to address the opioid crisis to prescribers in Weymouth.

150. Ironically, Purdue sales representatives also regularly overstated and misstated the evidence for and impact of the abuse-deterrent features of these opioids. Specifically, Purdue detailers:

a. Claimed that Purdue's ADF opioids *prevent* tampering and that its ADF products could not be crushed or snorted.

b. Claimed that Purdue's ADF opioids *reduce* opioid abuse and diversion.

c. Asserted or suggested that Purdue's ADF opioids are "safer" than other opioids.

d. Failed to disclose that Purdue's ADF opioids do not impact oral abuse or misuse.

151. These statements and omissions by Purdue are false and misleading and are inconsistent with the FDA-approved labels for Purdue's ADF opioids—which indicate that abusers seek them because of their high likeability when snorted, that their abuse deterrent properties can be defeated, and that they can be abused orally notwithstanding their abuse-deterrent properties, and which do *not* indicate that ADF opioids prevent or reduce abuse, misuse, or diversion.

152. Purdue knew or should have known that "reformulated OxyContin is not better at

tamper resistance than the original OxyContin"[41] and is still regularly tampered with and abused. Websites and message boards used by drug abusers, such as bluelight.org and reddit.com, also report a variety of ways to tamper with OxyContin and Hysingla ER, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which a tablet is dissolved. A publicly available Citizen Petition submitted to the FDA in 2016 by a drug manufacturing firm challenged Purdue's abuse-deterrent labeling based on the firm's ability to easily prepare so-called abuse deterrent OxyContin to be snorted or injected.

153. Further, *one-third* of the patients in a 2015 study defeated the ADF mechanism and were able to continue inhaling or injecting the drug. According to a Weymouth treatment center provider, it is very common for patients to be able to tamper with opioids with ADF properties. To the extent that the abuse of Purdue's ADF opioids was reduced, those addicts simply shifted to other drugs such as heroin.

154. A 2013 article presented by Purdue employees based on review of data from poison control centers, while concluding that ADF OxyContin can reduce abuse, ignored important negative findings. The study reveals that abuse merely shifted to other drugs and that, when the actual incidence of harmful exposures was calculated, there were *more* harmful exposures to opioids (including heroin) after the reformulation of OxyContin. In short, the article emphasized the advantages and ignored disadvantages of ADF OxyContin.

155. The CDC Guideline confirms that "*[n]o* studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies "do not prevent opioid abuse through oral intake, the most common route of

[41] *In re OxyContin*, 1:04-md-01603-SHS, Docket No 613, Oct. 7, 2013 hr'g, Testimony of Dr. Mohan Rao, 1615:7-10.

opioid abuse, and can still be abused by non-oral routes."[42] Tom Frieden, the Director of the CDC, reported that his staff could not find "any evidence showing the updated opioids (ADF opioids) actually reduce rates of addiction, overdoses, or death." [43]

156. In 2015, claiming a need to further assess its data, Purdue abruptly withdrew a supplemental new drug application related to reformulated OxyContin one day before FDA staff were to release its assessment of the application. The staff review preceded an FDA advisory committee meeting related to new studies by Purdue "evaluating the misuse and/or abuse of reformulated OxyContin" and whether those studies "have demonstrated that the reformulated product has a meaningful impact on abuse."[44] Upon information and belief, Purdue never presented the data to the FDA because the data would not have supported claims that OxyContin's ADF properties reduced abuse or misuse.

157. Yet despite the qualifying language in Purdue's label and its own evidence—and lack of evidence—regarding the impact of its ADF opioids in reducing abuse, Dr. J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's ADF opioids are being abused in large numbers.

2. Endo's deceptive marketing of reformulated Opana ER

158. In a strategy that closely resembled Purdue's, Endo, as the expiration of its patent exclusivity for Opana ER neared, and aware that it needed to be able to compete with other opioids, like OxyContin, that were being introduced in abuse-deterrent formulations, also made

[42] CDC Guideline at 22. (emphasis added).

[43] Matthew Perrone, *Drugmakers Push Profitable, but Unproven, Opioid Solution*, ASSOC. PRESS (Jan. 2, 2017), http://www.detroitnews.com/story/news/nation/2017/01/02/painkillers-drugmakers-addictive/96095558.

[44] Meeting Notice, Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee, May 25, 2015, 80 FR 30686.

abuse deterrence a key to its marketing strategy and its ability to maintain and increase profits from Opana ER.

159. In December 2011, Endo obtained approval for a new formulation of Opana ER that added a hard coating that the company claimed made it crush-resistant. Even prior to its approval, the FDA advised Endo in January 2011 that it would not be permitted to market Opana ER, even after the reformulation, as abuse-deterrent. The FDA found that such promotional claims "may provide a false sense of security since the product may be chewed and ground for subsequent abuse." In other words, Opana ER was still crushable. Indeed, in its approval package, Endo admitted that "[i]t has not been established that this new formulation of Opana ER is less subject to misuse, abuse, diversion, overdose, or addiction."

160. In August 2012, Endo submitted a confidential Citizen Petition asking the FDA for permission to change its label to indicate that Opana ER was abuse-resistant, both in that it was less able to be crushed and snorted, and that it was resistant to "aqueous extraction," or injection by syringe. Borrowing a page from Purdue's playbook, Endo announced it would withdraw original Opana ER from the market and sought a determination that its decision was made for safety reasons (its lack of abuse deterrence). That would prevent generic copies of original Opana ER from competitors, such as Impax Laboratories ("Impax"), which had sought approval to sell a generic version of the drug, and also help preserve the market for branded Opana ER, which could be sold at non-competitive prices.

161. Endo then sued the FDA, seeking to force expedited consideration of its Citizen Petition. The court filings confirmed its true motives: in a declaration submitted with its lawsuit, Endo's chief operating officer indicated that a generic version of Opana ER would decrease the company's revenue by up to $135 million per year. Endo also claimed that if the

FDA did not block generic competition, $125 million, which Endo spent on developing the reformulated drug to "promote the public welfare," would be lost.[45] The FDA responded that: "Endo's true interest in expedited FDA consideration stems from business concerns rather than protection of the public health."[46]

162. Meanwhile, despite Endo's purported concern with public safety, court filings indicate that not only did Endo continue to distribute original Opana ER for nine months after the reformulated version became available, it declined to recall original Opana ER despite its dangers. In fact, Endo also claimed in September 2012 to be "proud" that "almost all remaining inventory" of the original Opana ER had "been utilized."[47]

163. In its Citizen Petition, Endo asserted that redesigned Opana ER had "safety advantages." However, in rejecting the Petition in a 2013 decision, the FDA found that "study data show that the reformulated version's extended-release features can be compromised when subjected to ... cutting, grinding, or chewing." The FDA also determined that "reformulated Opana ER" could also be "readily prepared for injections and more easily injected[.]" In fact, the FDA warned that preliminary data—including in Endo's own studies—suggested that a higher percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation.

164. Over time, evidence confirmed that injection was becoming the preferred means of abusing Opana ER, which made Opana ER *less safe* than the original formulation. This

[45] Plaintiff's Opposition to Defendants' and Intervenor's Motions to Dismiss and Plaintiff's Reply in Support of Motion for Preliminary Injunction ("Endo Br."), *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al..*, No. 1:12-cv-01936 Doc. 23 at 20 (D.D.C. Dec.14, 2012).

[46] Defendants' Response to the Court's November 30, 2012 Order, *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al..*, No. 1:12-cv-01936 Doc. 9 at 6 (D.D.C. Dec. 3, 2012).

[47] *Id.*; Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl) *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al..*, No. 1:12-cv-01936 (Doc. 18-4) (D.D.C. Dec. 9, 2012).

occurred both because injection carries risks of HIV, Hepatitis C, and, in reformulated Opana ER's specific case, the blood-clotting disorder thrombotic thrombocytopenic purpura ("TTP"), which can cause kidney failure.[48] In 2009, only 3% of Opana ER abuse was by intravenous means. Since the reformulation, injection of Opana ER increased by more than 500% according to data gathered in 2017.

165. Nevertheless, Endo continued to market the drug as tamper-resistant and deterring abuse. Indeed, upon information and belief, detailers for Endo have informed doctors in Massachusetts that Opana ER was abuse-deterrent. In addition, upon information and belief, Endo sales representatives did not disclose evidence that Opana was easier to abuse intravenously and, if pressed by prescribers, claimed that while some outlying patients might find a way to abuse the drug, most would be protected.

166. Likewise, a review of nationally-collected surveys of prescribers regarding their "take-aways" from pharmaceutical detailing confirms that prescribers remember being told Opana ER was tamper-resistant, even after the May 2013 denial of Endo's Citizen Petition. Endo also tracked messages that doctors took from its in-person marketing. Among the advantages of Opana ER, according to participating doctors, was its "low abuse potential."

167. In its written materials, Endo marketed Opana ER as having been ***designed*** to be crush resistant, knowing that this would (falsely) imply that Opana ER actually ***was*** crush resistant and that this crush-resistant quality would make Opana ER less likely to be abused. For example, a June 14, 2012 Endo press release announced "the completion of the company's

[48] The CDC does not know why the redesigned Opana ER causes TTP, but it notes it did not appear in other prescription opioids prepared for injection. "Thrombotic Thrombocytopenic Purpura (TTP)–Like Illness Associated with Intravenous Opana ER Abuse—Tennessee, 2012," *Morbidity and Mortality Weekly Report* (Jan. 11, 2013). The CDC suggested it could be linked to inactive ingredients that make the product more difficult to crush or grind. No reports of Opana ER and TTP occurred prior to the reformulation.

transition of its OPANA ER franchise to the new formulation designed to be crush resistant."[49] The press release further stated that: "We firmly believe that the new formulation of OPANA ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians and payers."[50] In September 2012, another Endo press release stressed that reformulated Opana ER employed "INTAC Technology" and continued to describe the drug as "designed to be crush-resistant."[51] Similarly, journal advertisements that appeared in April 2013 stated Opana ER was "designed to be crush resistant." A January 2013 article in Pain Medicine News, based in part on an Endo press release, described Opana ER as "crush-resistant." This article was posted on the Pain Medicine News website, which was accessible to patients and prescribers nationally. In a 2016 settlement with Endo, the New York Attorney General ("NY AG") found that statements that Opana ER was "designed to be, or is crush resistant" were false and misleading because there was no difference in the ability to extract the narcotic from Opana ER. The NY AG also found that Endo failed to disclose its own knowledge of the crushability of redesigned Opana ER in its marketing to formulary committees and pharmacy benefit managers.

G. Defendants Deliberately Disregarded Their Duties to Maintain Effective Controls and to Identify, Report and Terminate Suspicious Orders

187. The Manufacturing Defendants created a vastly and dangerously larger market for opioids. All of the Defendants compounded this harm by facilitating the supply of far more opioids that could have been justified to serve that market. The failure of the Defendants to

[49] Ex. E to Rurka Decl., *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 12-v-1936, Doc. 18-2 at 1 (D.D.C. Dec. 9, 2012).

[50] *Id.*

[51] Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl) *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936 (Doc. 18-4) (D.D.C. Dec. 9, 2012).

maintain effective controls, and to investigate, report, and take steps to terminate orders that they knew or should have known were suspicious breached both their statutory and common law duties.

188. For over a decade, as the Manufacturing Defendants increased the demand for opioids, all the Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, Defendants are not permitted to engage in a limitless expansion of their sales through the unlawful sales of regulated painkillers. Rather, as described below, Defendants are subject to various duties to report the quantity of Schedule II controlled substances in order to monitor such substances and prevent oversupply and diversion into the illicit market.

1. All Defendants Have a Duty to Report Suspicious Orders and Terminate those Orders Unless Due Diligence Disproves Their Suspicions.

189. Multiple sources impose duties on the Defendants to report suspicious orders and further to not ship those orders unless due diligence disproves those suspicions.

190. First, under the common law, the Defendants had a duty to exercise reasonable care in delivering dangerous narcotic substances. By supplying Weymouth with more opioids than could be used for legitimate medical purposes and by filling and failing to report orders that they knew or should have realized were likely being diverted for illicit uses, Defendants breached that duty and both created and failed to prevent a foreseeable risk of harm to Weymouth.

191. Second, each of the Defendants assumed a duty, when speaking publicly about opioids and their efforts to combat diversion of prescription opioids, to speak accurately and truthfully.

192. Third, Defendants violated their statutory obligations under Massachusetts law and federal law. Defendants are all required to register as either manufacturers or distributors pursuant to Massachusetts law (*e.g.* M.G.L. c. 94C, § 7(a)), and federal law (21 U.S.C. § 823 and 21 C.F.R. §§ 1301.11, 1301.74). Federal regulations issued under the Controlled Substances Act (CSA) are incorporated into Massachusetts law pursuant to M.G.L. c. 94C, § 12(a)(2).

193. Recognizing a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States Congress enacted the CSA in 1970. The CSA and its implementing regulations created a closed-system of distribution for all controlled substances and listed chemicals. Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled substances into the illicit market. Congress was concerned with the diversion of drugs out of legitimate channels of distribution and acted to halt the "widespread diversion of [controlled substances] out of legitimate channels into the illegal market." Moreover, the closed-system was specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain. All registrants, including all manufacturers and distributors of controlled substances, must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion. When registrants at any level fail to fulfill their obligations, the necessary checks and balances collapse. The result is the scourge of addiction that has occurred.

194. The CSA requires manufacturers and distributors of Schedule II substances like opioids to: (a) limit sales within a quota set by the DEA for the overall production of Schedule II substances like opioids; (b) register to manufacture or distribute opioids; (c) maintain effective controls against diversion of the controlled substances that they manufacturer or distribute; and

(d) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA.

195. Central to the closed-system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from "legitimate channels of trade" by controlling the "quantities of the basic ingredients needed for the manufacture of [controlled substances], and the requirement of order forms for all transfers of these drugs." When evaluating production quotas, the DEA was instructed to consider the following information:

a. Information provided by the Department of Health and Human Services;

b. Total net disposal of the basic class [of each drug] by all manufacturers;

c. Trends in the national rate of disposal of the basic class [of drug];

d. An applicant's production cycle and current inventory position;

e. Total actual or estimated inventories of the class [of drug] and of all substances manufactured from the class and trends in inventory accumulation; and

f. Other factors such as: changes in the currently accepted medical use of substances manufactured for a basic class; the economic and physical availability of raw materials; yield and sustainability issues; potential disruptions to production; and unforeseen emergencies.

196. It is unlawful to manufacture a controlled substance in Schedule II, like prescription opioids, in excess of a quota assigned to that class of controlled substances by the DEA.

197. To ensure that even drugs produced within quota are not diverted, Federal regulations issued under the CSA mandate that all registrants, manufacturers and distributors alike, "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b). Registrants are not entitled to be passive (but profitable) observers, but rather "shall inform the Field Division Office of the Administration in his area of

suspicious orders when discovered by the registrant." *Id.* Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. *Id.* Other red flags may include, for example, "[o]rdering the same controlled substance from multiple distributors."

198. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a distributor or manufacturer need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the customer base and the patterns throughout the relevant segment of the industry. For this reason, identification of suspicious orders serves also to identify excessive volume of the controlled substance being shipped to a particular region.

199. These requirements are also adopted and incorporated into Massachusetts law. M.G.L. c. 94C, § 12(a)(2) (stating that as a registrant or licensee of Schedule II controlled substances, Distributor Defendants had a duty to comply with all applicable "federal, state, and local laws and regulations.").

200. As wholesale drug distributors of controlled substances, Distributor Defendants were required to register with the Massachusetts Commissioner of Public Health. M.G.L., c. 94C, § 7(a).

201. The Massachusetts Controlled Substances Act also requires that drug wholesalers must have "maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels." M.G.L. c. 94C, § 12(a)(1).

202. Massachusetts regulations, by virtue of requiring wholesale drug distributors who deal in controlled substances to register with the Massachusetts Commission of Public Health, and stating that such distributors maintain compliance with all applicable state, local laws" further mandate that suspicious orders, defined as unusual in size ***or*** frequency ***or*** deviation from buying patterns, be reported to the requisite authority. M.G.L. c. 94C, § 12(a)(2). Any of the red flags identified by law trigger a duty to report; however, this list is not exclusive. Other factors—such as whether the order is skewed toward high dose pills, or orders that are skewed towards drugs valued for abuse, rather than other high-volume drugs, such as cholesterol medicines, also should alert distributors to potential problems.

203. Distributors also have a duty to know their customers and the communities they serve. Through this process of customer due diligence, when a distributor observes suspicious circumstances—such as cash transactions or young and seemingly healthy patients filling prescriptions for opioids at a pharmacy they supply– it can trigger reasonable suspicion. A single order can warrant scrutiny, or it may be a pattern of orders, or an order that is unusual given the customer's history or its comparison to other customers in the area.

204. In sum, Defendants, due to the position of special trust and responsibility afforded them by their status as registrants in the distribution chain of controlled substances, have several responsibilities under state and federal law with respect to control of the supply chain of opioids. First, they must set up a system to prevent diversion, including excessive volume and other suspicious orders. That would include reviewing their own data, relying on their observations of

prescribers and pharmacies, and following up on reports or concerns of potential diversion. All suspicious orders must be reported to relevant enforcement authorities. Further, they must also stop shipment of any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, they can determine that the order is not likely to be diverted into illegal channels.

205. Massachusetts and federal statutes and regulations reflect a standard of conduct and care below which reasonably prudent manufacturers and distributors would not fall. Together, these laws and industry guidelines make clear that Distributor and Manufacturing Defendants alike possess and are expected to possess specialized and sophisticated knowledge, skill, information, and understanding of both the market for scheduled prescription narcotics and of the risks and dangers of the diversion of prescription narcotics when the supply chain is not properly controlled.

206. Further, these laws and industry guidelines make clear that the Distributor Defendants and Manufacturing Defendants alike have a duty and responsibility to exercise their specialized and sophisticated knowledge, information, skill, and understanding to prevent the oversupply of prescription opioids and minimize the risk of their diversion into an illicit market.

207. The FTC has recognized the unique role of Defendants McKesson, Cardinal, and AmerisourceBergen (the "Big Three"). Since their inception, the Big Three have continued to integrate vertically by acquiring businesses that are related to the distribution of pharmaceutical products and health care supplies. In addition to the actual distribution of pharmaceuticals, the Big Three also offer their pharmacy, or dispensing, customers a broad range of added services. For example, they offer their pharmacies sophisticated ordering systems and access to an inventory management system and distribution facility that allows customers to reduce

inventory-carrying costs. The Big Three are also able to use the combined purchase volume of their customers to negotiate the cost of goods with manufacturers and offer services that include software assistance and other database management support. *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998) (granting the FTC's motion for preliminary injunction and holding that the potential benefits to customers did not outweigh the potential anti-competitive effect of a proposed merger between Cardinal Health, Inc. and Bergen Brunswig Corp.). As a result of their acquisition of a diverse assortment of related businesses within the pharmaceutical industry, as well as the assortment of additional services they offer, the Big Three have a unique insight into the ordering patterns and activities of their dispensing customers.

208. Like the Big Three, Walgreens is also uniquely positioned to know the ordering patterns and activities of its dispensing customers due to its role as both a distributor and a national retail pharmacy. As a national retail pharmacy, Walgreens had a vertically integrated model, which placed it in a unique role, as it had both specific obligations under the CSA and a particular ability to spot, report, and stop filling suspicious orders. National retail pharmacies, like other distributors, are registrants under the CSA. 21 C.F.R. § 1301.11. Under the CSA, pharmacy registrants are required to "provide effective controls and procedures to guard against theft and diversion of controlled substances." *See* 21 C.F.R. § 1301.71(a). In addition, 21 C.F.R. § 1306.04(a) states, "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." Because pharmacies themselves are registrants under the CSA, the duty to prevent diversion lies with the pharmacy entity, not the individual pharmacist alone.

209. The DEA, among others, has provided extensive guidance to pharmacies concerning their duties to the public. The guidance advises pharmacies how to identify suspicious orders and other evidence of diversion.

210. Suspicious pharmacy orders include orders of unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern and/or orders of unusual frequency and duration, among others.

211. Additional types of suspicious orders include: (1) prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities or higher doses) for controlled substances compared to other practitioners in the area; (2) prescriptions which should last for a month in legitimate use, but are being refilled on a shorter basis; (3) prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time; (4) prescriptions that look "too good" or where the prescriber's handwriting is too legible; (5) prescriptions with quantities or doses that differ from usual medical usage; (6) prescriptions that do not comply with standard abbreviations and/or contain no abbreviations; (7) photocopied prescriptions; or 8) prescriptions containing different handwriting. Most of the time, these attributes are not difficult to detect and should be easily recognizable by pharmacies.

212. Suspicious pharmacy orders are red flags for if not direct evidence of diversion.

213. Other signs of diversion can be observed through data gathered, consolidated, and analyzed by Walgreens itself. That data allows it to observe patterns or instances of dispensing that are potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in improper prescribing. Indeed, this data is sufficiently valuable in identifying "high prescribers" for purposes of marketing efforts, that

companies such as IMS Health, Dendrite, Verispan, and Wolters Kluwer, referred to as "information distribution companies," "health information organizations" or "data vendors" purchase prescription records from pharmacies.[52] The majority of pharmacies sell these records.[53]

214. According to industry standards, if a pharmacy finds evidence of prescription diversion, the local Board of Pharmacy and DEA must be contacted.

215. Manufacturing Defendants also have specialized and detailed knowledge of the potential suspicious prescribing and dispensing of opioids through their regular visits to doctors' offices and pharmacies, and from their purchase of data from commercial sources, such as IMS. Their extensive boots-on-the-ground through their sales force, allows Manufacturing Defendants to observe the signs of suspicious prescribing, such as lines of seemingly healthy patients, out-of-state license plates, and cash transactions, to name only a few. In addition, Manufacturing Defendants regularly mined data, including, upon information, chargeback data, that allowed them to monitor the volume and type of prescribing of doctors, including sudden increases in prescribing and unusual high dose prescribing, that would have alerted them, independent of their sales representatives, to suspicious prescribing. These information points gave Manufacturing Defendants insight into prescribing and dispensing conduct that enabled them to play a valuable role in the preventing diversion and fulfilling their obligations under the CSA.

216. Defendants have a duty to, and are expected, to be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes.

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[52] Joint Appendix, *Sorrell v. IMS Health*, No. 10-779, 2011 WL 687134, at *388-89 (D.C. Cir. Feb. 22, 2011); (Fugh-Berman A, Ahari S (2007) *Following the Script: How Drug Reps Make Friends and Influence Doctors.* PLoS Med 4(4): e150. doi:10.1371/journal.pmed.0040150).

[53] *Id.* at 389.

217. Defendants breached these duties by failing to: (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; and (d) halt shipments of opioids in quantities they knew or should have known could not be justified and were indicative of serious problems of overuse of opioids.

2. Defendants Understood the Importance of Their Reporting Obligations

218. The reason for the reporting rules is to create a "closed" system intended to control the supply and reduce the diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control. Both because distributors handle such large volumes of controlled substances, and because they are uniquely positioned, based on their knowledge of their customers and orders, as the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, distributors' obligation to maintain effective controls to prevent diversion of controlled substances is critical. Should a distributor deviate from these checks and balances, the closed system of distribution, designed to prevent diversion, collapses.

219. All Defendants were well aware that they had an important role to play in this system, and also knew or should have known that their failure to comply with their obligations would have serious consequences.

220. Recently, Mallinckrodt, a prescription opioid manufacturer, admitted in a settlement with DEA that "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA."[54] Mallinckrodt further stated that it

[54] https://www.justice.gov/usao-edmi/press-release/file/986026/download

"recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and agreed that it would "design and operate a system that meets the requirements of 21 CFR 1301.74(b) ... [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product." Mallinckrodt specifically agreed "to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."

221. Trade organizations to which Defendants belong have acknowledged that wholesale distributors have been responsible for reporting suspicious orders for more than 40 years. The Healthcare Distribution Management Association ("HDMA," now known as the Healthcare Distribution Alliance ("HDA")), a trade association to which the Big Three (and Manufacturing Defendants) belong, and the National Association of Chain Drug Stores ("NACDS"), where Walgreens sits on the Board of Directors, have long taken the position that distributors have responsibilities to "prevent diversion of controlled prescription drugs" not only because they have statutory and regulatory obligations do so, but "as responsible members of society."[55] Guidelines established by the HDA also explain that distributors, "[a]t the center of a sophisticated supply chain ... are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers."[56]

222. The DEA also repeatedly reminded the Defendants of their obligations under

[55] *See Amicus Curiae* Br. of Healthcare Distribution Management Association (HDMA) in Support of Cardinal Health, Inc.'s Motion for Injunction Pending Appeal, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 at 4; Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharmaceuticals, Inc. v. Drug Enforcement Administration*, 2012 WL 1321983, at *2 (D.C. Cir. Apr. 4, 2016).

[56] Healthcare Distribution Management Association (HDMA) *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, filed in Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B at 1).

federal law, mirrored in and incorporated by Massachusetts law, to report and decline to fill suspicious orders. Responding to the proliferation of pharmacies operating on the internet that arranged illicit sales of enormous volumes of opioids to drug dealers and customers, the DEA began a major push to remind distributors of their obligations to prevent these kinds of abuses and educate them on how to meet these obligations. Since 2007, the DEA has hosted at least five conferences that provided registrants with updated information about diversion trends and regulatory changes.[57] The Big Three Distributor Defendants have each attended at least one of these conferences. The DEA has also briefed wholesalers regarding legal, regulatory, and due diligence responsibilities since 2006. During these briefings, the DEA pointed out the red flags wholesale distributors should look for to identify potential diversion.

223. The DEA also advised in a September 27, 2006 letter to every commercial entity registered to distribute controlled substances that they are "one of the key components of the distribution chain. If the closed system is to function properly ... distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as ... the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."[58] The DEA's September 27, 2006 letter also expressly reminded them that

[57] Drug Enf't Admin., *Distributor Conferences*: https://www.deadiversion.usdoj.gov/mtgs/distributor/index.html; Drug Enf't Admin., *Manufacturer Conferences*, https://www.deadiversion.usdoj.gov/mtgs/man_imp_exp/index.html; Drug Enf't Admin., *National Conference on Pharmaceutical and Chemical Diversion*, https://www.deadiversion.usdoj.gov/mtgs/drug_chemical/index.html; Drug Enf't Admin., *Diversion Awareness Conferences*, https://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/index.html.

[58] *See* 2006 Rannazzisi Letter ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.").

registrants, in addition to reporting suspicious orders, have a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."[59] The same letter reminds distributors of the importance of their obligation to "be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes," and warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."[60]

224. The DEA sent another letter to Defendants on December 27, 2007, reminding them that, as registered manufacturers and distributors of controlled substances, they share, and must each abide by, statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[61] The DEA's December 27, 2007 letter reiterated the obligation to detect, report, and not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and how to report (*e.g.*, by specifically identifying an order as suspicious, not merely transmitting data to the DEA). Finally, the letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."[62]

[59] *See id.*

[60] *See id.*

[61] *See* 2007 Rannazzisi Letter.

[62] *See id.*

3. Despite Repeated Admonitions, Defendants Have Repeatedly Violated their Obligations

225. Distributor Defendants have faced repeated enforcement actions for their failure to comply with their obligations to report and decline suspicious orders, making clear both that they were repeatedly reminded of their duties, and that they frequently failed to meet them.

226. Governmental agencies and regulators have confirmed (and in some cases Distributor Defendants have admitted) that Distributor Defendants did not meet their obligations, and have uncovered especially blatant wrongdoing.

227. In May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012. These included a number of actions against AmerisourceBergen, Cardinal, McKesson, and Walgreens:

a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

b. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, the DEA issued an *Order to Show Cause* against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* ("2008 McKesson MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

g. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn, Lakeland, Swedesboro and Stafford Facilities. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

h. On September 30, 2009, the DEA issued an Order to Show Cause against the Walgreens retail facility in San Diego, California.

i. In April 2011, Walgreens entered into an Administrative Memorandum of Agreement ("MOA") with the DEA in relation to its San Diego facility. The MOA provided that "Walgreens agrees to maintain a compliance program to detect and prevent diversion of controlled substances as required under the Controlled Substances Act ("CSA") and applicable DEA regulations."

j. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health's Lakeland Facility for failure to maintain effective controls against diversion of oxycodone;

k. On September 14, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Walgreens' Distribution Center in Jupiter, Florida.

l. On June 11, 2013, Walgreens agreed to pay $80 million in civil penalties to resolve the DEA's investigations. It also entered into another Memorandum of Agreement with the DEA in which it acknowledged that its distribution and dispensing practices were not fully consistent with its obligations under the CSA.

m. On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center.

228. In 2012, the State of West Virginia sued AmerisourceBergen and Cardinal Health, as well as several smaller wholesalers, for numerous causes of action, including violations of the CSA, consumer credit and protection, and antitrust laws and the creation of a public nuisance. Unsealed court records from that case demonstrate that AmerisourceBergen, along with McKesson and Cardinal Health, together shipped 423 million pain pills to West Virginia between 2007 and 2012. AmerisourceBergen itself shipped 80.3 million hydrocodone pills and 38.4 million oxycodone pills during that time period. These quantities alone are sufficient to show that Distributor Defendants failed to control the supply chain or to report and take steps to halt suspicious orders. In 2016, AmerisourceBergen agreed to settle the West Virginia lawsuit for $16 million to the state; Cardinal Health settled for $20 million.

229. More recently, Defendant McKesson admitted to breach of its duties to monitor, report, and prevent suspicious orders. Pursuant to an Administrative Memorandum of Agreement ("2017 Agreement") entered into between McKesson and the DEA in January 2017, McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters."[63] Further, the 2017 Agreement specifically finds that McKesson "distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled

[63] Settlement Agreement and Release between the U.S. and McKesson Corp., at 5 (Jan. 17, 2017) (hereinafter "2017 Settlement Agreement and Release") ("McKesson acknowledges that, at various times during the Covered Time Period [2009-2017], it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA."), available at https://www.justice.gov/opa/press-release/file/928471/download.

substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a)."[64] McKesson admitted that, during this time period, it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 *et seq.*, at the McKesson Distribution Centers".

230. As the Washington Post and *60 Minutes* recently reported, DEA staff recommended a much larger penalty, as much as a billion dollars, and delicensing of certain facilities.[65] A DEA memo outlining the investigative findings in connection with the administrative case against 12 McKesson distribution centers included in the 2017 Settlement stated that McKesson "[s]upplied controlled substances in support of criminal diversion activities"; "[i]gnored blatant diversion"; had a "[p]attern of raising thresholds arbitrarily"; "[f]ailed to review orders or suspicious activity"; and "[i]gnored [the company's] own procedures designed to prevent diversion."[66] The Washington Court House distribution center was among the warehouses investigators found "were supplying pharmacies that sold to criminal drug rings."[67]

231. Even the far lessor-than recommended civil penalty against McKesson, a $150 million fine, was record breaking. In addition to the monetary penalty, the DOJ required

[64] *Id.*

[65] Lenny Bernstein and Scott Higham, "'*We Feel Like Our System Was Hijacked': DEA Agents Say a Huge Opioid Case Ended in a Whimper*, WASHINGTON POST (Dec. 17, 2017).

[66] *Id.*

[67] *Id.*

McKesson to suspend sales of controlled substances from distribution centers in four different states. Though this penalty too, was far less severe than investigators had recommended, as the DOJ explained, these "staged suspensions" are nevertheless "among the most severe sanctions ever agreed to by a [Drug Enforcement Administration] registered distributor."[68]

232. In short, McKesson, was "neither rehabilitated nor deterred by the 2008 [agreement]," as a DEA official working on the case noted.[69] Quite the opposite, "their bad acts continued and escalated to a level of egregiousness not seen before."[70] According to statements of "DEA investigators, agents and supervisors who worked on the McKesson case" reported in the WASHINGTON POST, "the company paid little or no attention to the unusually large and frequent orders placed by pharmacies, some of them knowingly supplying the drug rings."[71] "Instead, the DEA officials said, the company raised its own self-imposed limits, known as thresholds, on orders from pharmacies and continued to ship increasing amounts of drugs in the face of numerous red flags."[72]

233. Further, in a *60 Minutes* interview last fall, former DEA agent Joe Rannazzisi described Wholesaler Defendants' industry as "out of control," stating that "[w]hat they wanna

[68] Department of Justice, "*McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs*," (Jan. 17, 2017) https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders.

[69] *Id.* (alteration in original).

[70] *Id.* (quoting a March 30, 2015 DEA memo).

[71] *Id.*

[72] *Id.*

do, is do what they wanna do, and not worry about what the law is. And if they don't follow the law in drug supply, people die. That's just it. People die."[73] He further explained that:

> JOE RANNAZZISI: The three largest distributors are Cardinal Health, McKesson, and AmerisourceBergen. They control probably 85 or 90 percent of the drugs going downstream.
>
> [INTERVIEWER]: You know the implication of what you're saying, that these big companies knew that they were pumping drugs into American communities that were killing people.
>
> JOE RANNAZZISI: That's not an implication, that's a fact. That's exactly what they did.[74]

234. Another DEA veteran similarly stated that these companies failed to make even a "good faith effort" to "do the right thing."[75] He further explained that "I can tell you with 100 percent accuracy that we were in there on multiple occasions trying to get them to change their behavior. And they just flat out ignored us."[76]

235. At a hearing before the House of Representatives' Energy and Committee Subcommittee on Oversight and Investigations on May 8, 2018, the chief executives of McKesson and Cardinal, among others, testified regarding their anti-diversion programs and their roles in the opioid epidemic. The Chairman of Miami-Luken alone acknowledged, in response to questions, that his company failed in the past to maintain effective controls to prevent diversion and that its actions contributed to the opioid crisis. He also testified that Miami-Luken had severed relationships with many customers that continue to do business with

[73] Bill Whitaker, *Ex-DEA Agent: Opioid Crisis Fueled by Drug Industry and* Congress, CBS News (Oct. 17, 1017), https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-Congress

[74] *Id.*

[75] *Id.*

[76] *Id.*

other distributors. Despite the frequent prior enforcement actions described above, neither McKesson nor Cardinal admitted any deficiencies in their compliance. In fact, both executives' answers confirmed gaps and breakdowns in past and current practices.

236. For example, Cardinal's former Executive Chairman, George Barrett, denied that **"**volume in relation to size of population" is a "determining factor" in identifying potentially suspicious orders. Despite regulatory and agency direction to identify, report, and halt suspicious *orders*, Cardinal focused on whether a pharmacy was legitimate, not whether its orders suggested evidence of diversion. Despite a Cardinal employee flagging an especially prolific pharmacy as a potential pill mill in 2008, the Subcommittee found no evidence that Cardinal took any action in response. In addition, Cardinal increased another pharmacy's threshold twelve times, but could not explain what factors it applied or how it made decisions to increase thresholds.

237. According to records produced to the Subcommittee, McKesson's due diligence file on one of the pharmacies in West Virginia that it supplied with a massive volume of opioids consisted of only two pages. Despite McKesson's claim that it (a) reviewed every single customer for high volume orders of certain drugs; (b) set a threshold of 8,000 pills per month; and (c) examined and documented every order over that threshold, the company still shipped 36 times the monthly threshold to one pharmacy—more than 9,500 pills *per day*.

238. Further, as referenced above, Walgreens has also been repeatedly penalized for its illegal prescription opioid practices. Upon information and belief, based upon the widespread nature of these violations, these enforcement actions are the product of, and confirm, national policies and practices of the Walgreens.

239. Walgreens is the second-largest pharmacy store chain in the United States behind CVS, with annual revenue of more than $118 billion. According to its website, Walgreens operates more than 8,100 retail locations and filled 990 million prescriptions on a 30-day adjusted basis in fiscal 2017.

240. Walgreens also has been penalized for serious and flagrant violations of the CSA. Indeed, Walgreens agreed to the largest settlement in DEA history—$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the CSA, including negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black market sales.[77]

241. The settlement resolved investigations into and allegations of CSA violations in Florida, New York, Michigan, and Colorado that resulted in the diversion of millions of opioids into illicit channels.

242. Walgreens' Florida operations at issue in this settlement highlight its egregious conduct regarding diversion of prescription opioids. Walgreens' Florida pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011—more than ten times the average amount.[78]

243. They increased their orders over time, in some cases as much as 600% in the space of just two years, including, for example, supplying a town of 3,000 with 285,800 orders of oxycodone in a one-month period. Yet Walgreens corporate officers turned a blind eye to

[77] Press Release, U.S. Attorney's Office S. Dist. of Fla., *Walgreens Agrees To Pay A Record Settlement Of $80 Million For Civil Penalties Under The Controlled Substances Act*, U.S. Dep't of Just. (June 11, 2013), https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-record-settlement-80-million-civil-penalties-under-controlled

[78] Order to Show Cause and Immediate Suspension of Registration, *In the Matter of Walgreens Co.*, (Drug Enf't Admin. Sept. 13, 2012).

these abuses. In fact, corporate attorneys at Walgreens suggested, in reviewing the legitimacy of prescriptions coming from pain clinics, that "if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance," underscoring Walgreens' attitude that profit outweighed compliance with the CSA or the health of communities.[79]

244. Defendant Walgreens' settlement with the DEA stemmed from the DEA's investigation into Walgreens' distribution center in Jupiter, Florida, which was responsible for significant opioid diversion in Florida. According to the Order to Show Cause, Defendant Walgreens' corporate headquarters pushed to increase the number of oxycodone sales to Walgreens' Florida pharmacies, and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales. In July 2010, Defendant Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in June of that year, and found that the highest-ranking store in oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center.[80]

245. Walgreens has also settled with a number of state attorneys general, including West Virginia ($575,000) and Massachusetts ($200,000).

246. The Massachusetts Attorney General's Medicaid Fraud Division found that, from 2010 through most of 2015, multiple Walgreens stores across the state failed to monitor the opioid use of some Medicaid patients who were considered high-risk.

[79] *Id*.

[80] *Id*.

247. In January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients' drug use patterns and did not use sound professional judgment when dispensing opioids and other controlled substances—despite the context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay $200,000 and follow certain procedures for dispensing opioids.[81]

248. Manufacturers had knowledge of diversion as well and have failed to comply with their obligations to report and decline suspicious orders. Sales representatives learned that the prescription opioids they were promoting were being diverted, often with lethal consequences. As a sales representative wrote on a public forum:

> Actions have consequences—so some patient gets Rx'd the 80mg OxyContin when they probably could have done okay on the 20mg (but their doctor got "sold" on the 80mg) and their teen son/daughter/child's teen friend finds the pill bottle and takes out a few 80's... next they're at a pill party with other teens and some kid picks out a green pill from the bowl... they go to sleep and don't wake up (because they don't understand respiratory depression) Stupid decision for a teen to make...yes... but do they really deserve to die?

249. Moreover, Manufacturing Defendants' sales incentives rewarded sales representatives who happened to have pill mills within their territories, enticing those representatives to look the other way even when their in-person visits to such clinics should have raised numerous red flags. In one example, a pain clinic in South Carolina was diverting massive quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away to get prescriptions, the DEA's diversion unit raided the clinic, and prosecutors eventually filed criminal charges against the doctors. But Purdue's sales representative for that territory, Eric Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another

[81] *Id*.

local physician that this clinic accounted for 40% of the OxyContin sales in his territory. At that time, Wilson was Purdue's top-ranked sales representative. In response to news stories about this clinic, Purdue issued a statement, declaring that "if a doctor is intent on prescribing our medication inappropriately, such activity would continue regardless of whether we contacted the doctor or not."[82]

250. In another example, a Purdue sales manager informed her supervisors in 2009 about a suspected pill mill in Los Angeles, reporting over email that when she visited the clinic with her sales representative, "it was packed with a line out the door, with people who looked like gang members," and that she felt "very certain that this an organized drug ring[.]"[83] She wrote, "This is clearly diversion. Shouldn't the DEA be contacted about this?" But her supervisor at Purdue responded that while they were "considering all angles," it was "really up to [the wholesaler] to make the report."[84] This pill mill was the source of 1.1 million pills trafficked to Everett, Washington, a city of around 100,000 people. Purdue waited until after the clinic was shut down in 2010 to inform the authorities.

251. Manufacturing Defendants' obligation to report suspicious prescribing ran head on into their marketing strategy. These Defendants did identify doctors who were their most prolific prescribers, but not to report them - to market to them. It would make little sense to focus on marketing to doctors who may be engaged in improper prescribing only to report them to law enforcement, nor to report those doctors who drove Defendants' sales.

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[82] Meier, *Pain Killer*.

[83] Harriet Ryan et al., *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew*, LOS ANGELES TIMES (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/

[84] *Id.*

252. Whenever examples of opioid diversion and abuse have drawn media attention, Purdue and other Manufacturing Defendants have consistently blamed "bad actors." For example, in 2001, during a Congressional hearing, Purdue's attorney Howard Udell answered pointed questions about how it was that Purdue could utilize IMS Health data to assess their marketing efforts but not notice a particularly egregious pill mill in Pennsylvania run by a doctor named Richard Paolino. Udell asserted that Purdue was "fooled" by the doctor: "The picture that is painted in the newspaper [of Dr. Paolino] is of a horrible, bad actor, someone who preyed upon this community, who caused untold suffering. And he fooled us all. He fooled law enforcement. He fooled the DEA. He fooled local law enforcement. He fooled us."[85]

253. But given the closeness with which Defendants monitored prescribing patterns through IMS Health data, it is highly improbable that they were "fooled." In fact, a local pharmacist had noticed the volume of prescriptions coming from Paolino's clinic and alerted authorities. Purdue had the prescribing data from the clinic and alerted no one. Indeed, a Purdue executive referred to Purdue's tracking system and database as a "gold mine" and acknowledged that Purdue could identify highly suspicious volumes of prescriptions.

H. Defendants Worked Together To Sustain Their Market and Boost Their Profits

254. The Big Three, as leading wholesale distributors, had close financial relationships with both manufacturers and customers, for whom they provide a broad range of value added services that render them uniquely positioned to obtain information and control against diversion. These services often otherwise would not be provided by manufacturers to their downstream customers who ultimately dispense the drugs and would be difficult and costly for the dispenser to reproduce. For example, "[w]holesalers have sophisticated ordering systems

[85] Meier, *Pain Killer*, at 179.

that allow customers to electronically order and confirm their purchases, as well as to confirm the availability and prices of wholesalers' stock." *Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998). Through their generic source programs, wholesalers are also able "to combine the purchase volumes of customers and negotiate the cost of goods with manufacturers." Wholesalers also offer marketing programs, patient services, and other software to assist their dispensing customers.

255. Distributor Defendants had financial incentives from manufacturers to distribute higher volumes, and thus to refrain from reporting or declining to fill suspicious orders. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors. Decreased cost per pill in turn, allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit. Either way, the increased sales volumes result in increased profits.

256. Upon information and belief, each of the Distributor Defendants also worked together, and with Manufacturing Defendants, through trade or other organizations, such as the HDA, the National Association of Chain Drugstores, and the Pain Care Forum ("PCF"), to safeguard the market for opioids and the distribution of opioids.[86]

[86] https://www.documentcloud.org/documents/3108980-PAIN-CARE-FORUM-Directory-04-2012.html (2012 document showing defendants or parents/affiliates)

257. Although the entire HDA membership directory is private, the HDA website confirms that Defendants AmerisourceBergen, Cardinal, and McKesson, were members.[87] All of the Manufacturing Defendants were members as well.[88]

258. The closed meetings of the HDA's councils, committees, task forces and working groups provided the Big Three with the opportunity to work closely with each other and with opioid manufacturers, confidentially, to develop and further their common purpose and interests.

259. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributors advertise these conferences as an opportunity to "bring together high-level executives, thought leaders and influential managers ... to hold strategic business discussions on the most pressing industry issues."[89] The conferences also gave the Distributors and Manufacturing Defendants "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry."[90] The HDA and its conferences were significant opportunities for the Big Three to interact at a high level of leadership.

260. HDA members were eligible to participate on councils, committees, task forces and working groups, including:

a. Industry Relations Council: "This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues."

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[87] https://www.healthcaredistribution.org/about/membership/distributor (H.D. Smith would have been represented by Smith Drug Company, Div. J M Smith Corporation.)

[88] https://www.healthcaredistribution.org/about/membership/manufacturer

[89] *Business and Leadership Conference—Information for Manufacturers*, Healthcare Distribution Alliance, *available at* (https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers last accessed on Sept. 14, 2017).

[90] *Id.*

b. Business Technology Committee: "This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee's major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce." Participation in this committee includes distributors and manufacturer members.

c. Logistics Operation Committee: "This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement." Participation in this committee includes distributors and manufacturer members.

d. Manufacturer Government Affairs Advisory Committee: "This committee provides a forum for briefing HDA's manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement." Participation in this committee includes manufacturer members.

e. Contracts and Chargebacks Working Group: "This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals." Participation in this group includes manufacturer and distributor members.[91]

261. The Distributor Defendants and Manufacturing Defendants also participated, through the HDA, in Webinars and other meetings designed to exchange detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices. For example, on April 27, 2011, the HDA offered a Webinar to "accurately and effectively exchange business transactions between distributors and manufacturers…" Upon information and belief, the Manufacturing Defendants used this

[91] Councils and Committees, Healthcare Distribution Alliance, (accessed on December 11, 2017), available at https://www.healthcaredistribution.org/about/councils-and-committees

information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell prescription opioids.

262. The Big Three also coordinated with each other and opioid manufacturers in other ways, including, according to articles published by the Center for Public Integrity and the Associated Press, the Pain Care Forum—whose members include, upon information and belief, the HDA—has been lobbying on behalf of opioid manufacturers and distributors for "more than a decade."[92] This coordination in their lobbying further supports an inference that Defendants worked together in other ways, as is described in this Complaint.

263. Distributor Defendants also worked together through HDA and National Association of Chain Drugstores ("NACDS"). The respective CEOs of the HDA and NACDS have spoken with one voice, with respect to portraying their members as committed to safeguarding the integrity of the supply chain when opposing efforts to promote the importation of prescription drugs as a means of mitigating the escalating costs of medications. These statements support the inference that Distributor Defendants worked together in other ways as well to mislead the public regarding their commitment to complying with their legal obligations and safeguarding against diversion.

264. Taken together, the interaction and length of the relationships between and among the Marketing and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry. The Marketing and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed

[92] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (Sept. 19, 2017), available at https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic; PAIN CARE FORUM 2012 Meetings Schedule, (last updated Dec. 2011) (showing Covidien, Mallinckrodt LLC's parent company until mid-2013, as a member in 2012), available at https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf

system. Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

265. Publications and guidelines issued by the HDA confirm that the Defendants utilized their membership in the HDA to form agreements. Specifically, in the fall 2008, the HDA published the Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances (the "Industry Compliance Guidelines") regarding diversion. As the HDA explained in an amicus brief, the Industry Compliance Guidelines were the result of "[a] committee of HDMA members contribut[ing] to the development of this publication" beginning in late 2007.

266. This statement by the HDA and the Industry Compliance Guidelines support the allegation that Defendants utilized the HDA to form agreements about their approach to their duties under the CSA. As John M. Gray, President/CEO of the HDA stated to the Energy and Commerce Subcommittee on Health in April 2014, is "difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications." Here, it is apparent that Defendants found the same balance – an overwhelming pattern and practice of failing to identify, report, or halt suspicious orders, and failure to prevent diversion.

267. The Defendants worked together to control the flow of information and influence state and federal governments to pass legislation that supported the use of opioids and limited the authority of law enforcement to rein in illicit or inappropriate prescribing and distribution. The Manufacturing and Distributor Defendants did this through their participation in the PCF, HDA, and the NACDS.

268. Upon information and belief, the Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA remained artificially high and ensured that suspicious orders were not reported to the DEA in order to ensure that the DEA had no basis for refusing to increase or decrease production quotas due to diversion.

269. The Defendants also had reciprocal obligations under the CSA to report suspicious orders of other parties if they became aware of them. Defendants thus knew that their own conduct could be reported by other distributors or manufacturers and that their failure to report suspicious orders they filled could be brought to the DEA's attention. As a result, Defendants had an incentive to communicate with each other about the reporting of suspicious orders to ensure consistency in their dealings with DEA.

270. The desired consistency was achieved. As described below, none of the Defendants reported suspicious orders and the flow of opioids continued unimpeded.

I. Defendants Ignored Red Flags Of Abuse and Diversion

271. The data that reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA's confidential ARCOS database.[93] The data necessary to identify with specificity the transactions that were suspicious is in possession of the Distributor Defendants and Manufacturing Defendants, but has not been disclosed to the public.

272. Yet, publicly available information confirms that Defendants funneled far more opioids into Weymouth than could have been expected to serve legitimate medical use, and ignored other red flags of suspicious orders. This information, along with the information known

[93] *See Madel v. USDOJ*, 784 F.3d 448 (8th Cir. 2015).

only to Defendants, would have alerted them to potentially suspicious orders of opioids in and affecting Weymouth.

273. Weymouth's information and belief rests upon the following facts:

a. Distributors have access to detailed transaction-level data on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and pharmacy and includes the volume of opioids, dose, and the distribution of other controlled and non-controlled substances.

b. The Big Three, Manufacturing Defendants regularly visit pharmacies and/or doctors to promote and provide their products and services, which allows them to observe red flags of diversion. Similarly, Walgreens has direct access to the transaction data of its chain of retail pharmacies.

c. The Big Three together may account for more than 90% of all revenues from prescription drug distribution in the United States, and each plays such a large part in the distribution of opioids that its own volume provides a ready vehicle for measuring the overall flow of opioids into a pharmacy or geographic area;

d. Walgreens has been relatedly penalized for their illegal prescription opioid practices, and the wide-spread nature of these violations suggests they are the product of national policies and practices;

e. Performance metrics and prescription quotas adopted by the national retail pharmacies such as Walgreens for their retail stores contributed to their failure. The result is both deeply troubling and entirely predictable: opioids flowed out of national retail pharmacies and into communities throughout the country. The policies remained in place even as the epidemic raged.

274. At all relevant times, Defendants were in possession of data or information that allowed them to track prescribing patterns over time. Walgreens, for example, had direct access to the prescription rates of its retail pharmacies.

275. Distributors have a duty to know their customers and the communities they serve. Wholesale distributors, such as the Big Three, developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007, was intended to help distributors identify suspicious orders or customers who were likely to

divert prescription opioids.[94] The "know your customer" questionnaires informed distributors of the number of pills that the pharmacies sold, how many non-controlled substances were sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

276. According to testimony by a Cardinal former Executive Chairman of the Board at a hearing before the House of Representatives' Energy and Committee Subcommittee on Oversight and Investigations on May 8, 2018, a distributor has the ability to request drug dispensing reports, which include all drugs dispensed by a pharmacy, not only those by Cardinal, and had requested such reports in the past. Upon information and belief, other wholesale distributors could request similar reports, and, as explained above, Walgreens would have had this information from their own pharmacies.

277. Given this, and the additional red flags described below, Defendants should have been on notice that the diversion of opioids was likely occurring in and around Weymouth, should have investigated, terminated suspicious orders, and reported potential diversion to law enforcement.

278. In addition, between 2010 and 2016, an average of 222.65mg of oxycodone were dispersed per Norfolk County resident.[95]

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[94] *Suggested Questions a Distributor should ask prior to shipping controlled substances,* Drug Enforcement Administration (*available at* https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf); Richard Widup, Jr., Kathleen H. Dooley, Esq., *Pharmaceutical Production Diversion: Beyond the PDMA,* Purdue Pharma and McGuireWoods LLC, (*available at* https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf).

[95] Public ARCOS data.

279. A former Mallinckrodt sales representative had offices in Weymouth, the criminally indicted doctor, Fathallah Mashali, over the course of 5 years. During those visits the Mallinckrodt representative saw the doctor's office overflowing with patients, some of whom waited for up to 8 hours to see the doctor, and heard them bragging about earning $70,000 from selling prescriptions written by the doctor. Despite having around 300 doctors on his call list, the former sales representative's supervisor at Mallinckrodt instructed the sales representative to spend half of his time with the doctor because of the sales potential due to the doctor's prescribing. Though the sales representative and his supervisor acknowledged not wanting Mallinckrodt to be connected to the doctor, they decided not to report the doctor.

280. Upon information and belief, this prescriber and others like him, and the pharmacies at which their patients filled prescriptions for opioids, yielded orders of unusual size, frequency, or deviation, or raised other warning signs that should have alerted Defendants not only to an overall oversupply in the Weymouth area, but to specific instances of diversion. Yet, there is no indication that Defendants reported these doctors or pharmacies to law enforcement or medical or pharmacy boards.

281. In addition, Weymouth has been greatly affected by both fatal and non-fatal overdoses from opioids. Many of these deaths are attributable to prescription opioids, and increasingly, to illicit opiates, to which people who have become addicted to prescription opioids often transition. In 2015, there were 183 non-fatal overdoses related to opioids. This number jumped to 219 non-fatal opioid-related overdoses in 2016. Additionally, in 2015, opioid related deaths claimed 24 lives in Weymouth. In 2016, this number increased to 38 opioid-related deaths. The CDC estimates that for every opioid-related death, there are 733 non-medical users. Defendants thus had every reason to believe that illegal diversion was occurring in Weymouth.

282. Based upon these red flags, and the Distributor Defendants' ability to obtain dispensing information from its customers, it can be fairly inferred that Defendants had information about suspicious orders that they did not report, and also failed to exercise due diligence before filling orders from which drugs were diverted into illicit uses in Weymouth.

J. Defendants Hid Their Lack Of Cooperation With Law Enforcement and Falsely Claimed To Be Actively Working To Prevent Diversion

283. When a wholesaler or manufacturer does not report or stop suspicious orders, prescriptions for controlled substances may be written and dispensed to individuals who abuse them or who sell them to others to abuse. This, in turn, fuels and expands the illegal market and results in opioid-related overdoses. Without reporting by those involved in the supply chain, law enforcement may be delayed in taking action – or may not know to take action at all.

284. After being caught failing to comply with particular obligations at particular facilities, Distributor Defendants made broad promises to change their ways and insisted that they sought to be good corporate citizens. As part of McKesson's 2008 Settlement with the DEA, McKesson claimed to have "taken steps to prevent such conduct from occurring in the future," including specific measures delineated in a "Compliance Addendum" to the Settlement. Yet, in 2017, McKesson paid $150 million to resolve an investigation by the U.S. DOJ for again failing to report suspicious orders of certain drugs, including opioids.

285. More generally, the Defendants publically portrayed themselves as committed to working with law enforcement, opioid manufacturers, and others to prevent diversion of these dangerous drugs. For example, Defendant Cardinal claims that: "We challenge ourselves to best utilize our assets, expertise and influence to make our communities stronger and our world more sustainable, while governing our activities as a good corporate citizen in compliance with all

regulatory requirements and with a belief that doing 'the right thing' serves everyone."[96] Defendant Cardinal likewise claims to "lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse." Along the same lines, it claims to "maintain a sophisticated, state-of-the-art program to identify, block and report to regulators those orders of prescription controlled medications that do not meet [its] strict criteria."[97] Defendant Cardinal also promotes funding it provides for "Generation Rx," which funds grants related to prescription drug misuse.[98] A Cardinal executive recently claimed that Cardinal uses "advanced analytics" to monitor its supply chain; Cardinal assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[99]

286. Along the same lines, Defendant McKesson publicly claims that its "customized analytics solutions track pharmaceutical product storage, handling and dispensing in real time at every step of the supply chain process," creating the impression that McKesson uses this tracking to help prevent diversion.[100] Defendant McKesson has also publicly stated that it has a "best-in-

[96] Cardinal website, Ethics and Governance, available at http://www.cardinalhealth.com/en/about-us/corporate-citizenship/ethics-and-governance.html.

[97] Cardinal website, Archives, Cardinal Health Values Statement, available at http://cardinalhealth.mediaroom.com/valuestatement.

[98] Cardinal website, available at http://www.cardinalhealth.com/en/about-us/corporate-citizenship/community-relations/population-health/rx-drug-misuse-and-abuse.html.

[99] Lenny Bernstein et al., How Drugs Intended for Patients Ended up in the Hands of Illegal Users: 'No one was doing their job', THE WASHINGTON POST (Oct. 22,2016), http://wapo.st/2vCRGLt.

[100] McKesson website, Pharmaceutical Distribution for Manufacturers, available at http://www.mckesson.com/manufacturers/pharmaceutical-distribution/.

class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."[101]

287. Defendant AmerisourceBergen, too, has taken the public position that it is "work[ing] diligently to combat diversion and [is] working closely with regulatory agencies and other partners in pharmaceutical and healthcare delivery to help find solutions that will support appropriate access while limiting misuse of controlled substances."[102] A company spokeswoman also provided assurance that: "At AmerisourceBergen, we are committed to the safe and efficient delivery of controlled substances to meet the medical needs of patients."[103]

288. Walgreens, too, publicly portrays itself as committed to working diligently to prevent diversion of these dangerous drugs and curb the opioid epidemic, including through installation of safe-disposal kits at Walgreens pharmacies and plans to make Naloxone available without a prescription. Citing these efforts, Walgreens promotes itself as committed to undertaking "a comprehensive national plan announced earlier this year to address key contributors to the crisis."

289. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, Defendants, through their trade associations, the HDMA and the NACDS, filed an *amicus* brief in *Masters Pharmaceuticals*, which made the following statements:[104]

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[101] Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, THE WASHINGTON POST, Dec. 22, 2016, available at https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html.

[102] https://www.wvgazettemail.com/news/cops_and_courts/drug-firms-fueled-pill-mills-in-rural-wv/article_14c8e1a5-19b1-579d-9ed5-770f09589a22.html

[103] https://www.wvgazettemail.com/news/cops_and_courts/drug-firms-fueled-pill-mills-in-rural-wv/article_14c8e1a5-19b1-579d-9ed5-770f09589a22.html

[104] Brief for HDMA and NACDS, 2016 WL 1321983, at *3-4, *25 (D.C. Cir. Apr. 4, 2016).

a. "HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."

b. "Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process."

290. Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, Distributor Defendants not only acknowledged that they understood their obligations under the law, but they further affirmed that their conduct was in compliance with those obligations.

291. These public statements created the false and misleading impression that the Distributor Defendants rigorously carried out their duty to report suspicious orders and exercise due diligence to prevent diversion of these dangerous drugs, and also worked voluntarily to prevent diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact.

292. Manufacturing Defendants also misrepresented their compliance with their legal duties and their cooperation with law enforcement. Purdue serves as a hallmark example of such wrongful conduct. Purdue deceptively and unfairly failed to report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its "constructive role in the fight against opioid abuse," including its commitment to ADF opioids and its "strong record of coordination with law enforcement."[105]

[105] Purdue, *Setting The Record Straight On OxyContin's FDA-Approved Label*, May 5, 2016, available at http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontins-fda-approved-label/

Purdue, *Setting The Record Straight On Our Anti-Diversion Programs*, July 11, 2016, available at http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/.

293. At the heart of Purdue's public outreach is the claim that it works hand-in-glove with law enforcement and government agencies to combat opioid abuse and diversion. Purdue has consistently trumpeted this partnership since at least 2008, and the message of close cooperation is in virtually all of Purdue's recent pronouncements in response to the opioid abuse.

294. Touting the benefits of ADF opioids, Purdue's website asserts: "[W]e are acutely aware of the public health risks these powerful medications create ... . That's why we work with health experts, law enforcement, and government agencies on efforts to reduce the risks of opioid abuse and misuse ... ."[106] Purdue's statement on "Opioids Corporate Responsibility" likewise states that "[f]or many years, Purdue has committed substantial resources to combat opioid abuse by partnering with ... communities, law enforcement, and government."[107] And, responding to criticism of Purdue's failure to report suspicious prescribing to government regulatory and enforcement authorities, the website similarly proclaims that Purdue "ha[s] a long record of close coordination with the DEA and other law enforcement stakeholders to detect and reduce drug diversion."[108]

295. These public pronouncements create the misimpression that Purdue is proactively working with law enforcement and government authorities nationwide to root out drug diversion, including the illicit prescribing that can lead to diversion. It aims to distance Purdue from its

[106] Purdue website, *Opioids With Abuse-Deterrent Properties*, available at http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/

[107] Purdue website, *Opioids Corporate Responsibility*, available at http://www.purduepharma.com/news-media/opioids-corporate-responsibility.

[108] Purdue, *Setting The Record Straight On Our Anti-Diversion Programs*, July 11, 2016, available at http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/. Contrary to its public statements, Purdue seems to have worked behind the scenes to push back against law enforcement.

past conduct in deceptively marketing opioids and make its current marketing seem more trustworthy and truthful.

296. Public statements by the Defendants and their associates created the false and misleading impression to regulators, prescribers, and the public that the Defendants rigorously carried out their legal duties, including their duty to report suspicious orders and exercise due diligence to prevent diversion of these dangerous drugs, and further created the false impression that these Defendants also worked voluntarily to prevent diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact.

K. By Increasing Opioid Prescriptions and Use, Defendants Collectively Fueled The Opioid Epidemic And Significantly Harmed Weymouth and its Residents

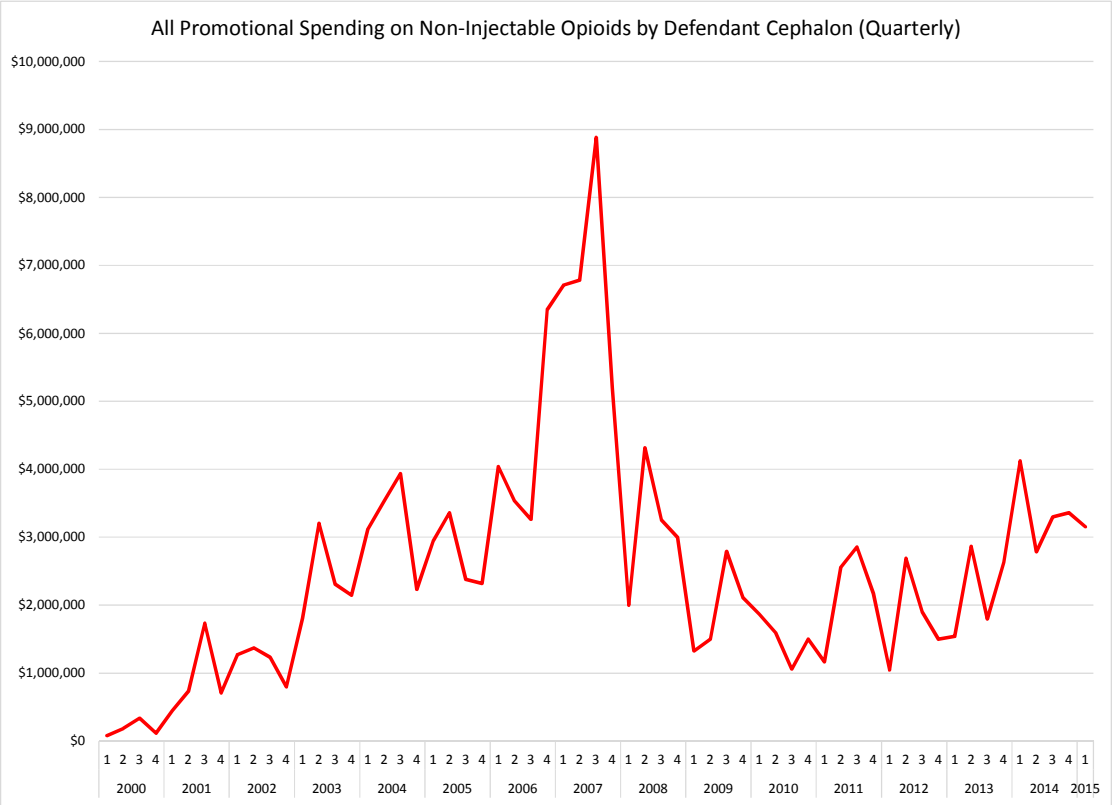
297. Manufacturing Defendants' misrepresentations prompted Weymouth health care providers to prescribe, patients to take, and payors to cover opioids for the treatment of chronic pain. Through their marketing, Manufacturing Defendants overcame barriers to widespread prescribing of opioids for chronic pain with deceptive messages about the risks and benefits of long-term opioid use. The Distributor Defendants recklessly distributed opioids and failed to meet their regulatory obligations in Massachusetts.

298. Defendants' deceptive marketing and illegal distribution practices substantially contributed to an explosion in the use of opioids across the country. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are the most common treatment for chronic pain. Since 2016, 20% of office visits have included the prescription of an opioid.

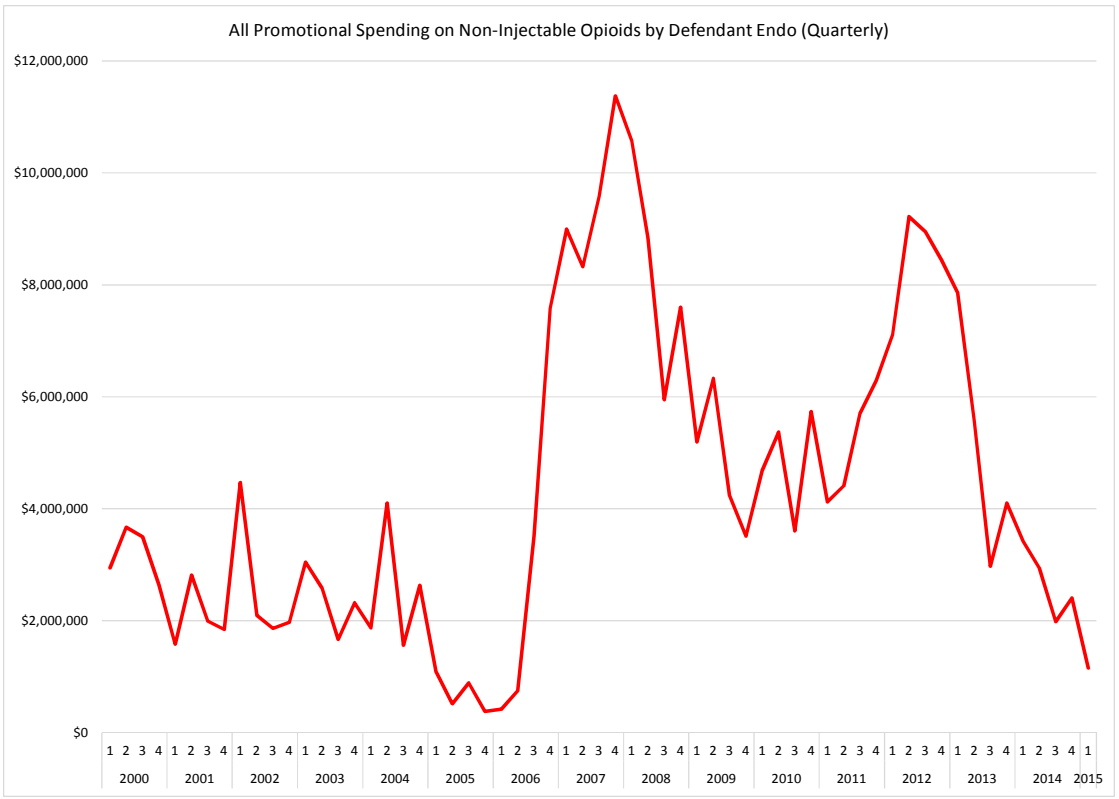
299. Manufacturing Defendants devoted and continue to devote massive resources to direct sales contacts with doctors. In 2014 alone, Manufacturing Defendants spent $166 million on detailing branded opioids to doctors. This amount is twice as much as Manufacturing

Defendants spent on detailing in 2000. The amount includes $108 million spent by Purdue, $34 million by Janssen, $13 million by Teva, and $10 million by Endo.

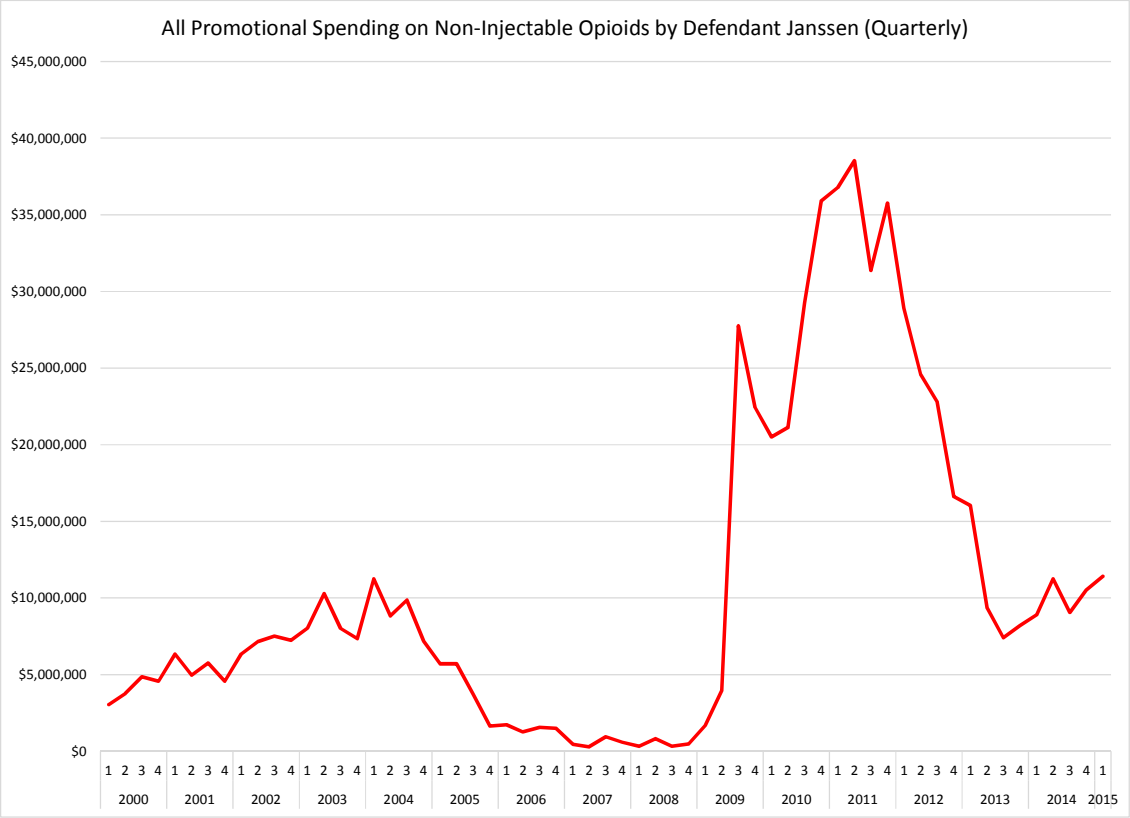
300. Teva's quarterly national spending steadily climbed from below $1 million in 2000 to more than $3 million in 2014 (and more than $13 million for the year), with a peak, coinciding with the launch of Fentora, of nearly $9 million for one quarter of 2007 (and more than $27 million for the year), as shown below:



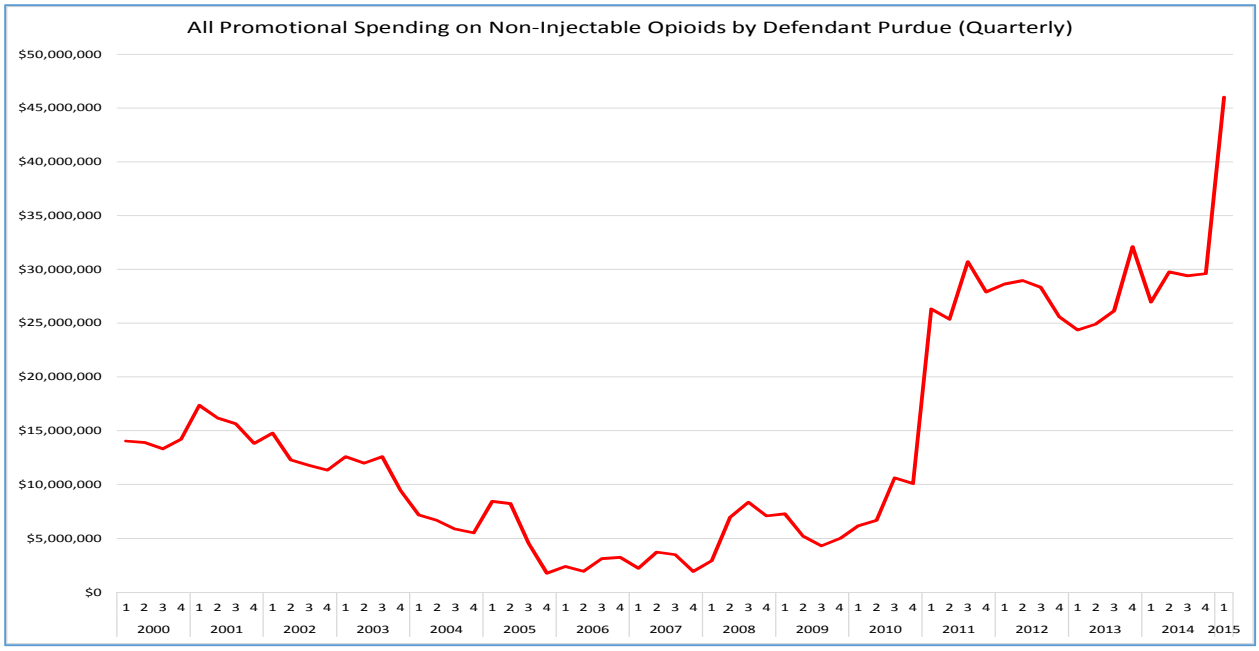
302. Endo's quarterly spending went from the $2 million to $4 million range in 2000-2004 to more than $10 million following the launch of Opana ER in mid-2006 (and more than $38 million for the year in 2007) and more than $8 million coinciding with the launch of a reformulated version in 2012 (and nearly $34 million for the year):


All Promotional Spending on Non-Injectable Opioids by Defendant Endo (Quarterly)
$12,000,000
$10,000,000
$8,000,000
$6,000,000
$4,000,000
$2,000,000
$0
1 2 3 4
2000
2001
2002
2003
2004
2005
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015

303. Janssen's quarterly spending dramatically rose from less than $5 million in 2000 to more than $30 million in 2011, coinciding with the launch of Nucynta ER (with yearly spending at $142 million for 2011), as shown below:



304. Purdue's quarterly spending notably decreased from 2000 to 2007, as Purdue came under investigation by the Department of Justice, but then spiked to above $25 million in 2011 (for a total of $110 million that year), and continued to rise through at least 2015, as shown below:



305. The sharp increase in opioid use resulting from Defendants' conduct has led directly to a dramatic increase in opioid abuse, addiction, overdose, and death throughout the United States, including in Weymouth. Representing the NIH's National Institute of Drug Abuse in hearings before the Senate Caucus on International Narcotics Control in May 2014, Dr. Nora Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem."[109]

[109] *America's Addiction to Opioids: Heroin and Prescription Drug Abuse: Hearing before the Senate Caucus on Int'l Narcotics Control*, May 14, 2014 Hr'g Testimony of Dr. Nora Volkow, available at http://www.drugcaucus.senate.gov/sites/default/files/Volkow%20Testimony.pdf.

306. In August 2016, then U.S. Surgeon General Vivek Murthy published an open letter to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors ... . [m]any of [whom] were even taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain."[110]

307. Chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain—has become a commonplace, and often first-line, treatment. Manufacturing Defendants' deceptive marketing caused prescribing not only of their opioids, but of opioids as a class, to skyrocket. According to the CDC, opioid prescriptions, as measured by number of prescriptions and morphine milligram equivalent ("MME") per person, tripled from 1999 to 2015. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the U.S. While previously a small minority of opioid sales, today between 80% and 90% of opioids (measured by weight) used are for chronic pain. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are the most common treatment for chronic pain, and 20% of office visits now include the prescription of an opioid.

308. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical

[110] *See* Murthy, *supra* note 2.

"to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."[111]

309. Scientific evidence demonstrates a close link between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse."[112]

310. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."[113] The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[114]

311. Weymouth has experienced an increase in opioid-related overdoses. In 2015, Weymouth's first responders received 183 calls due to opioid-related overdoses. In 2016 this number increased to 219 calls. Nationwide, opioids were involved in 42% of all fatal drug overdoses in 2015, and another 25% involved heroin. According to the CDC, between 1999 and 2015, more than 194,000 people died in the United States from prescription-related overdoses. Weymouth has experienced deaths due to opioid-related overdoses. In 2015, opioid related deaths claimed 24 lives in Weymouth. In 2016, this number increased to 38, opioid-related deaths. In August 2017, the Weymouth Police and town substance abuse committee held a vigil

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[111] CDC, January 1, 2016 Morbidity and Mortality Weekly Report; Rudd, Rose A., *Increases in drug and opioid overdose deaths—United States, 2000–2014,* AM. J. OF TRANSPLANTATION 16.4 (2016): 1323-1327.

[112] Theodore J. Cicero *et al*., *Relationship Between Therapeutic Use and Abuse* of *Opioid Analgesics in Rural, Suburban, and Urban* Locations in the United States, 16.8 PHARMACOEPIDEMIOLOGY AND DRUG SAFETY, 827-40 (2007).

[113] Dart, MD, *et al.*, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, NEW ENGL. J. MED., 372:241-248 (Jan. 15, 2015).

[114] Califf, MD, *et al.*, *A Proactive Response to Prescription Opioid Abuse,* NEW ENGL. J. MED. (Apr. 14, 2016).

at a local park for Weymouth families and residents who had been impacted by the opioid epidemic. According to the Weymouth Substance Abuse Prevention Coordinator, the vigil was intended to offer healing to lost loved ones from overdose deaths, and to those impacted by the opioid epidemic. Through a written statement on the vigil, the Coordinator stated, "While we continue to deal with this crisis, it is important that we remember the lives that have been lost and the real human impact that these drugs have had on our community … It will also be a time to highlight the hope that exists for those who are in recovery." Over 400 Weymouth residents attended the vigil. From January 1, 2019 to March 21, 2019, there were 4 opioid-related deaths.

312. The loss of each of these individuals cannot be adequately conveyed by statistics, nor can the depth and breadth of the impact on those who survive. Because the addictive pull of opioids is so strong, relapse is more common than with other drugs. Weymouth has experienced an increase in Narcan administration. In 2015, Weymouth's first responders administered 114 units of Narcan, and this number increased to 138 units in 2016. In 2017, the use administration of Narcan jumped to 150 units administered for the year.

313. Rising opioid use and abuse have negative social and economic consequences far beyond overdoses. According to a recent analysis by a Princeton University economist, approximately one out of every three working age men who are not in the labor force take daily prescription pain medication. The same research finds that opioid prescribing alone accounts for 20% of the overall decline in the labor force participation for this group from 2014-16, and 25% of the smaller decline in labor force participation among women. Many of those taking painkillers still said they experienced pain daily.

314. The abuse of opioids causes additional medical conditions as well. A growing number of people need medications aimed at treating secondary effects of opioids—including

not only addiction and overdose, but also side effects like constipation and sedation. According to a recent analysis by the WASHINGTON POST, working-age women and men on opioids are much more likely to have four or more prescriptions from a physician (57% and 41%, respectively) than their counterparts who do not take opioids (14% and 9%, respectively). These secondary-effect medications—essentially, drugs to treat the effects of opioids—generated at least $4.6 billion in spending nationally in 2015, on top of $9.57 billion in spending on opioids themselves.

315. The deceptive marketing and overprescribing of opioids also had a significant detrimental impact on children. Prescription opioid use before high school graduation is related to a 33% increase in the risk of later opioid misuse. Additionally, the adolescent misuse of opioid medications greatly predicts the later use of heroin. However, according to the CDC Guidelines, there has been a significant increase in the prescribing of opioids to adolescents and children for headaches and injuries. Upon information and belief, children and adolescents in Weymouth have been prescribed opioid prescriptions for various injuries.

316. Additionally, a Weymouth child was recently hospitalized for ingesting an opioid pill. In January 2018, a two-year-old-girl was taken to Boston Children's hospital for ingesting a synthetic opioid pill. The girl's parents saw an open pill bottle near the girl, and called first responders when they noticed that she acted lethargic. The girl was determined to be in stable condition, but remained at the hospital for observation.

317. Even infants have not been immune to the impact of opioid abuse. There has been a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome ("NAS," also known as neonatal opioid withdrawal syndrome, or "NOWS"). These infants painfully withdraw from the drug once they

are born, cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. The long-term developmental effects are still unknown, though research in other states has indicated that these children are likely to suffer from continued, serious neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction. When untreated, NAS can be life-threatening. In 2009, more than 13,000 infants in the United States were born with NAS, or about one every hour.

318. NAS rates in Weymouth have steadily increased on the past few years. In 2013, a Weymouth-area hospital saw an average of 59 cases of NAS per 1,000 births, which was more than triple the state average that year.

319. In addition, an increasing number of children in Weymouth have entered into foster care because their parents or caregivers are addicted to opioids. A couple who live near Weymouth were both nurses in Weymouth-area hospital neonatal intensive care units, also have fostered 16 children, most of whom who were born with drug exposure. The couple has noticed an increase in orphaned and sickened babies born in area hospitals due to the opioid-crisis, and that many babies born in the NICU who suffer from NAS wait for weeks and even months for a foster family.

320. Defendants' success in extending the market for opioids to new patients and chronic conditions also created an abundance of drugs available for non-medical or criminal use and fueled a new wave of addiction, abuse, and injury.

321. Contrary to Defendants' misrepresentations, most of the illicit use originates from *prescribed* opioids. It has been estimated that 60% of the opioids that are abused come, directly

or indirectly, through physicians' prescriptions. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from drug dealers or the internet.

322. Those who are addicted to prescription opioid painkillers are 40 times more likely to be addicted to heroin. The CDC identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. The heroin epidemic has directly impacted Weymouth. In May 2017, a Weymouth man and another man were arrested for heroin distribution for distributing the drug in Weymouth. When arrested, the Weymouth resident was found with a plastic bag with several grams of heroin inside. The Weymouth Police Narcotics Unit and the drug task force conducted months-long investigation into the man as well as into the drug trafficking organization that supplied him with the heroin.

323. Fentanyl is a relatively recent, even more deadly problem stemming from the prescription opioid epidemic. Fentanyl—a powerful opioid prescribed for cancer pain or in hospital settings that, in synthetic form, has made its way into communities across the country. As recently as March 2019, two Weymouth women were charged with trafficking more than 10 grams of fentanyl and for conspiracy to violate drug laws. Police spent two months investigating the women and watched them complete several drug transactions from one of the women's Weymouth home. According to the Weymouth police department, fentanyl and fentanyl mixed with heroin have become popular drugs for drug dealers but it is both cheap and deadly.

324. Weymouth has experienced intense crime due to the opioid epidemic. In October 2016, the Weymouth police department made two opioid-related arrests in one day—one for selling fentanyl as heroin and the other for selling heroin.

325. In light of this crippling epidemic, Weymouth has instituted a number of cutting edge programs aimed at curbing addiction and abuse. For example, Weymouth has received

grants for substance abuse treatment and prevention. From 2011 until 2017, Weymouth spent over $1 million from a federal Drug Free Communities grant, and used this grant to combat the devastation that Weymouth has faced due to the opioid crisis. Through these grants, Weymouth has created several initiatives that include medication collection events, opiate prevention programs, a medication kiosk where residents are able to dispose of unwanted medications, a needle collection, community outreach and education events, the distribution of information to help residents identify signs and symptoms of prescription drug and heroin abuse, the creation of online, real-time data which reports opioid-related overdoses and the areas of the overdoses, and public service announcements on local cable channels.

L. Defendants Fraudulently Concealed Their Misconduct

326. Defendants made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their marketing was false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Manufacturing Defendants of this, and likewise, Purdue and Teva paid hundreds of millions of dollars to address similar misconduct that occurred before 2008. Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on existing medical evidence that conclusively exposes the known falsity of these Defendants' misrepresentations.

327. Notwithstanding this knowledge, at all times relevant to this Complaint, Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing

and unlawful and fraudulent conduct. Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through biased science, unbranded marketing, third party advocates, and professional associations. Purdue, Endo, Teva, and Janssen purposefully hid behind the assumed credibility of these sources and relied on them to establish the accuracy and integrity of Defendants' false and misleading messages about the risks and benefits of long-term opioid use for chronic pain. Purdue, Endo, Teva, and Janssen masked or never disclosed their role in shaping, editing, and approving the content of this information.

328. Manufacturing Defendants thus successfully concealed from the medical community, patients, and Weymouth facts sufficient to arouse suspicion of the claims that Weymouth now asserts. Weymouth did not know of the existence or scope of these Defendants' fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

329. The Distributor Defendants also fraudulently concealed their misconduct. They have declined to publicly release the ARCOS data which provides detailed tracking information about their shipments. In addition, as explained above, these Defendants publicly portray themselves as maintaining sophisticated technology as part of a concerted effort to thwart diversion, and publicly portray themselves as committed to fighting the opioid epidemic, while failing to prevent diversion.

330. Defendants thus successfully concealed from the medical community, patients, and the Commonwealth facts sufficient to arouse suspicion of the claims that Weymouth now asserts. Weymouth did not know of the existence or scope of these Defendants' fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

331. Further, Defendants misleadingly portrayed themselves as cooperating with law enforcement and actively working to combat the opioid epidemic when, in reality, Defendants failed to satisfy even their minimum, legally-required obligations to report suspicious prescribers and pharmacy orders.

FACTS PERTAINING TO CLAIMS UNDER RACKETEER-INFLUENCED AND CORRUPT ORGANIZATIONS ("RICO") ACT

M. The Opioid Marketing Enterprise

1. The Common Purpose and Scheme of the Opioid Marketing Enterprise

332. Knowing that their products were highly addictive, ineffective and unsafe for the treatment of long-term chronic pain, non-acute and non-cancer pain, the RICO Marketing Defendants[115] formed an association-in-fact enterprise and engaged in a scheme to unlawfully increase their profits and sales, and grow their share of the prescription painkiller market, through repeated and systematic misrepresentations about the safety and efficacy of opioids for treating long-term chronic pain.

333. In order to unlawfully increase the demand for opioids, the RICO Marketing Defendants formed an association-in-fact enterprise (the "Opioid Marketing Enterprise") with the "Front Groups" (APF, AAPM, APS, and FSMB) and KOLs (Dr. Portenoy, Dr. Webster, Dr. Fine, and Dr. Fishman) described herein. Through their personal relationships, the members of the Opioid Marketing Enterprise had the opportunity to form and take actions in furtherance of the Opioid Marketing Enterprise's common purpose. The RICO Marketing Defendants' substantial financial contribution to the Opioid Marketing Enterprise, and the advancement of opioids-friendly messaging, fueled the U.S. opioids epidemic.

[115] The RICO Marketing Defendants referred to in this section are those named in Count VI under 28 U.S.C. § 1961 *et seq.* - Purdue, Teva, Janssen, and Endo.

334. The RICO Marketing Defendants, through the Opioid Marketing Enterprise, concealed the true risks and dangers of opioids from the medical community and the public, including Plaintiff, and made misleading statements and misrepresentations about opioids that downplayed the risk of addiction and exaggerated the benefits of opioid use. The misleading statements included: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition the Marketing Defendants named "pseudoaddiction"; (4) that withdrawal is easily managed; (5) that increased dosing present no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; and (9) that abuse-deterrent formulations provide a solution to opioid abuse.

335. The scheme devised, implemented and conducted by the RICO Marketing Defendants was a common course of conduct designed to ensure that the RICO Marketing Defendants unlawfully increased their sales and profits through concealment and misrepresentations about the addictive nature and effective use of the RICO Marketing Defendants' drugs. The RICO Marketing Defendants, the Front Groups, and the KOLs acted together for a common purpose and perpetuated the Opioid Marketing Enterprise's scheme, including through the unbranded promotion and marketing network as described above.

336. There was regular communication between the RICO Marketing Defendants, Front Groups and KOLs, in which information was shared, misrepresentations are coordinated, and payments were exchanged. Typically, the coordination, communication and payment occurred, and continues to occur, through the repeated and continuing use of the wires and mail

in which the RICO Marketing Defendants, Front Groups, and KOLs share information regarding overcoming objections and resistance to the use of opioids for chronic pain. The RICO Marketing Defendants, Front Groups and KOLs functioned as a continuing unit for the purpose of implementing the Opioid Marketing Enterprise's scheme and common purpose, and each agreed and took actions to hide the scheme and continue its existence.

337. At all relevant times, the Front Groups were aware of the RICO Marketing Defendants' conduct, were knowing and willing participants in and beneficiaries of that conduct. Each Front Group also knew, but did not disclose, that the other Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and the Plaintiff. But for the Opioid Marketing Enterprise's unlawful fraud, the Front Groups would have had incentive to disclose the deceit by the RICO Marketing Defendants and the Opioid Marketing Enterprise to their members and constituents. By failing to disclose this information, Front Groups perpetuated the Opioid Marketing Enterprise's scheme and common purpose, and reaped substantial benefits.

338. At all relevant times, the KOLs were aware of the RICO Marketing Defendants' conduct, were knowing and willing participants in that conduct, and reaped benefits from that conduct. The RICO Marketing Defendants selected KOLs solely because they favored the aggressive treatment of chronic pain with opioids. The RICO Marketing Defendants' support helped the KOLs become respected industry experts. And, as they rose to prominence, the KOLs falsely touted the benefits of using opioids to treat chronic pain, repaying the RICO Marketing Defendants by advancing their marketing goals. The KOLs also knew, but did not disclose, that the other KOLS and Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and the Plaintiff. But for the Opioid Marketing Enterprise's unlawful

conduct, the KOLs would have had incentive to disclose the deceit by the RICO Marketing Defendants and the Opioid Marketing Enterprise, and to protect their patients and the patients of other physicians. By failing to disclose this information, KOLs furthered the Opioid Marketing Enterprise's scheme and common purpose, and reaped substantial benefits.

339. As public scrutiny and media coverage focused on how opioids ravaged communities in Massachusetts and throughout the United States, the Front Groups and KOLs did not challenge the RICO Marketing Defendants' misrepresentations, seek to correct their previous misrepresentations, terminate their role in the Opioid Marketing Enterprise, nor disclose publicly that the risks of using opioids for chronic pain outweighed their benefits and were not supported by medically acceptable evidence.

340. The RICO Marketing Defendants, Front Groups and KOLs engaged in certain discrete categories of activities in furtherance of the common purpose of the Opioid Marketing Enterprise. As described herein, the Opioid Marketing Enterprise's conduct in furtherance of the common purpose of the Opioid Marketing Enterprise involved: (1) misrepresentations regarding the risk of addiction and safe use of prescription opioids for long-term chronic pain (described in detail above); (2) lobbying to defeat measures to restrict over-prescription; (3) efforts to criticize or undermine CDC guidelines; and (4) efforts to limit prescriber accountability.

341. In addition to disseminating misrepresentations about the risks and benefits of opioids, the Opioid Marketing Enterprise also furthered its common purpose by criticizing or undermining CDC guidelines. Members of the Opioid Marketing Enterprise criticized or undermined the CDC Guidelines which represented "an important step—and perhaps the first major step from the federal government—toward limiting opioid prescriptions for chronic pain."

342. Several Front Groups, including the U.S. Pain Foundation and the AAPM, criticized the draft guidelines in 2015, arguing that the "CDC slides presented on Wednesday were not transparent relative to process and failed to disclose the names, affiliation, and conflicts of interest of the individuals who participated in the construction of these guidelines."

343. The AAPM criticized the prescribing guidelines in 2016, through its immediate past president, stating "that the CDC guideline makes disproportionately strong recommendations based upon a narrowly selected portion of the available clinical evidence."

344. The RICO Marketing Defendants alone could not have accomplished the purpose of the Opioid Marketing Enterprise without the assistance of the Front Groups and KOLs, who were perceived as "neutral" and more "scientific" than the RICO Marketing Defendants themselves. Without the work of the Front Groups and KOLs in spreading misrepresentations about opioids, the Opioid Marketing Enterprise could not have achieved its common purpose.

345. The impact of the Opioid Marketing Enterprise's scheme is still in place—*i.e.*, the opioids continue to be prescribed and used for chronic pain throughout Weymouth and the epidemic continues to injure Plaintiff, and consume the resources of Plaintiff's health care and law enforcement systems.

346. As a result, it is clear that the RICO Marketing Defendants, the Front Groups, and the KOLs were each willing participants in the Opioid Marketing Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise's purpose.

2. The Conduct of the Opioid Marketing Enterprise violated Civil RICO

347. From approximately the late 1990s to the present, each of the RICO Marketing Defendants exerted control over the Opioid Marketing Enterprise and participated in the

operation or management of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. Creating and providing a body of deceptive, misleading and unsupported medical and popular literature about opioids that: (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

b. Creating and providing a body of deceptive, misleading and unsupported electronic and print advertisements about opioids that: (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

c. Creating and providing a body of deceptive, misleading and unsupported sales and promotional training materials about opioids that: (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

d. Creating and providing a body of deceptive, misleading and unsupported CMEs and speaker presentations about opioids that: (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

e. Selecting, cultivating, promoting and paying KOLs based solely on their willingness to communicate and distribute the Marketing Defendants' messages about the use of opioids for chronic pain;

f. Providing substantial opportunities for KOLs to participate in research studies on topics the RICO Marketing Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

g. Paying KOLs to serve as consultants or on the Marketing Defendants' advisory boards, on the advisory boards and in leadership positions on Front Groups, and to give talks or present CMEs, typically over meals or at conferences;

h. Selecting, cultivating, promoting, creating and paying Front Groups based solely on their willingness to communicate and distribute the RICO Marketing Defendants' messages about the use of opioids for chronic pain;

i. Providing substantial opportunities for Front Groups to participate in and/or publish research studies on topics the RICO Marketing Defendants suggested or chose (and paid for), with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

j. Paying significant amounts of money to the leaders and individuals associated with Front Groups;

k. Donating to Front Groups to support talks or CMEs, that were typically presented over meals or at conferences;

l. Disseminating many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications from Front Groups;

m. Sponsoring CME programs put on by Front Groups that focused exclusively on the use of opioids for chronic pain;

n. Developing and disseminating pro-opioid treatment guidelines with the help of the KOLs as authors and promoters, and the help of the Front Groups as publishers, and supporters;

o. Encouraging Front Groups to disseminate their pro-opioid messages to groups targeted by the RICO Marketing Defendants, such as veterans and the elderly, and then funding that distribution;

p. Concealing their relationship to and control of Front Groups and KOLs from the Plaintiff and the public at large; and

q. Intending that Front Groups and KOLs would distribute through the U.S. mail and interstate wire facilities, promotional and other materials that claimed opioids could be safely used for chronic pain.

348. The Opioid Marketing Enterprise had a hierarchical decision-making structure that was headed by the RICO Marketing Defendants and corroborated by the KOLs and Front Groups. The RICO Marketing Defendants controlled representations made about their opioids and their drugs, doled out funds to PBMs and payments to KOLs, and ensured that representations made by KOLs, Front Groups, and the RICO Marketing Defendants' sales detailers were consistent with the Marketing Defendants' messaging throughout the United States and Massachusetts. The Front Groups and KOLS in the Opioid Marketing Enterprise

were dependent on the Marketing Defendants for their financial structure and for career development and promotion opportunities.

349. The Front Groups also conducted and participated in the conduct of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. The Front Groups promised to, and did, make representations regarding opioids and the Marketing Defendants' drugs that were consistent with the Marketing Defendants' messages;

b. The Front Groups distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain outweighed the risks;

c. The Front Groups echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the Marketing Defendants;

d. The Front Groups issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;

e. The Front Groups strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and

f. The Front Groups concealed their connections to the KOLs and the Marketing Defendants.

350. The RICO Marketing Defendants' Front Groups, "with their large numbers and credibility with policymakers and the public—have 'extensive influence in specific disease areas.'" The larger Front Groups "likely have a substantial effect on policies relevant to their industry sponsors."[116] "By aligning medical culture with industry goals in this way, many of the

[116] *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Members' Office, February 12, 2018 https://www.hsdl.org/?abstract&did=808171

groups described in this report may have played a significant role in creating the necessary conditions for the U.S. opioid epidemic."[117]

351. The KOLs also participated in the conduct of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. The KOLs promised to, and did, make representations regarding opioids and the RICO Marketing Defendants' drugs that were consistent with the Marketing Defendants' messages themselves;

b. The KOLs distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain outweighed the risks;

c. The KOLs echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the RICO Marketing Defendants;

d. The KOLs issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;

e. The KOLs strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and

f. The KOLs concealed their connections to the Front Groups and the RICO Marketing Defendants, and their sponsorship by the Marketing Defendants.

352. The scheme devised and implemented by the RICO Marketing Defendants and members of the Opioid Marketing Enterprise, amounted to a common course of conduct intended to increase the RICO Marketing Defendants' sales from prescription opioids by encouraging the prescribing and use of opioids for long-term chronic pain. The scheme was a continuing course of conduct, and many aspects of it continue through to the present.

3. The Opioid Marketing Enterprise Defendants Controlled and Paid Front Groups and KOLs to Promote and Maximize Opioid Use

[117] *Id.* at 2.

353. As discussed in detail above, the Marketing Defendants funded and controlled the various Front Groups, including APF, AAPM/APS, FSMB, and Alliance for Patient Access. The Front Groups, which appeared to be independent, but were not, transmitted the RICO Marketing Defendants' misrepresentations. The RICO Marketing Defendants and the Front Groups thus worked together to promote the goals of the Opioid Marketing Enterprise.

354. The RICO Marketing Defendants worked together with each other through the Front Groups that they jointly funded and through which they collaborated on the joint promotional materials described above.

355. Similarly, as discussed in detail above, the RICO Marketing Defendants paid KOLs, including Drs. Portenoy, Fine, Fishman, and Webster, to spread their misrepresentations and promote their products. The RICO Marketing Defendants and the KOLs thus worked together to promote the goals of the Opioid Marketing Enterprise.

4. Pattern of Racketeering Activity

356. The RICO Marketing Defendants' scheme described herein was perpetrated, in part, through multiple acts of mail fraud and wire fraud, constituting a pattern of racketeering activity as described herein.

357. The pattern of racketeering activity used by the RICO Marketing Defendants and the Opioid Marketing Enterprise likely involved thousands of separate instances of the use of the U.S. Mail or interstate wire facilities in furtherance of the unlawful Opioid Marketing Enterprise, including essentially uniform misrepresentations, concealments and material omissions regarding the beneficial uses and non-addictive qualities for the long-term treatment of chronic, non-acute and non-cancer pain, with the goal of profiting from increased sales of the RICO Marketing Defendants' drugs induced by consumers, prescribers, regulators and Plaintiff's reliance on the Marketing Defendants' misrepresentations.

358. Each of these fraudulent mailings and interstate wire transmissions constitutes racketeering activity and collectively, these violations constitute a pattern of racketeering activity, through which the RICO Marketing Defendants, the Front Groups and the KOLs defrauded and intended to defraud Massachusetts consumers, the State, and other intended victims.

359. The RICO Marketing Defendants devised and knowingly carried out an illegal scheme and artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts regarding the safe, non-addictive and effective use of opioids for long-term chronic, non-acute and non-cancer pain. The RICO Marketing Defendants and members of the Opioid Marketing Enterprise knew that these representations violated the FDA approved use these drugs, and were not supported by actual evidence. The RICO Marketing Defendants intended that that their common purpose and scheme to defraud would, and did, use the U.S. Mail and interstate wire facilities, intentionally and knowingly with the specific intent to advance, and for the purpose of executing, their illegal scheme.

360. By intentionally concealing the material risks and affirmatively misrepresenting the benefits of using opioids for chronic pain to prescribers, regulators and the public, including Plaintiff, the RICO Marketing Defendants, the Front Groups and the KOLs engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

361. The RICO Marketing Defendants' use of the U.S. Mail and interstate wire facilities to perpetrate the opioids marketing scheme involved thousands of communications, publications, representations, statements, electronic transmissions, payments, including, inter alia:

g. Marketing materials about opioids, and their risks and benefits, which the RICO Marketing Defendants sent to health care providers, transmitted through the internet and television, published, and transmitted to Front Groups and KOLs located across the country and the State;

h. Written representations and telephone calls between the RICO Marketing Defendants and Front Groups regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;

i. Written representations and telephone calls between the RICO Marketing Defendants and KOLs regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;

j. E-mails, telephone and written communications between the RICO Marketing Defendants and the Front Groups agreeing to or implementing the opioids marketing scheme;

k. E-mails, telephone and written communications between the RICO Marketing Defendants and the KOLs agreeing to or implementing the opioids marketing scheme;

l. Communications between the RICO Marketing Defendants, Front Groups and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Enterprise;

m. Communications between the RICO Marketing Defendants, KOLs and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Enterprise;

n. Written and oral communications directed to State agencies, federal and state courts, and private insurers throughout the State that fraudulently misrepresented the risks and benefits of using opioids for chronic pain; and

o. Receipts of increased profits sent through the U.S. Mail and interstate wire facilities—the wrongful proceeds of the scheme.

362. In addition to the above-referenced predicate acts, it was intended by and foreseeable to the RICO Marketing Defendants that the Front Groups and the KOLs would distribute publications through the U.S. Mail and by interstate wire facilities, and, in those publications, claim that the benefits of using opioids for chronic pain outweighed the risks of doing so.

363. To achieve the common goal and purpose of the Opioid Marketing Enterprise, the RICO Marketing Defendants and members of the Opioid Marketing Enterprise hid from the consumers, prescribers, regulators and the Plaintiff: (a) the fraudulent nature of the RICO Marketing Defendants' marketing scheme; (b) the fraudulent nature of statements made by the RICO Marketing Defendants and by their KOLs, Front Groups and other third parties regarding the safety and efficacy of prescription opioids; and (c) the true nature of the relationship between the members of the Opioid Marketing Enterprise.

364. The RICO Marketing Defendants, and each member of the Opioid Marketing Enterprise agreed, with knowledge and intent, to the overall objective of the RICO Marketing Defendants' fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in marketing prescription opioids.

365. Indeed, for the RICO Marketing Defendants' fraudulent scheme to work, each of them had to agree to implement similar tactics regarding fraudulent marketing of prescription opioids. This conclusion is supported by the fact that the RICO Marketing Defendants each financed, supported, and worked through the same KOLs and Front Groups, and often collaborated on and mutually supported the same publications, CMEs, presentations, and prescription guidelines.

366. The RICO Marketing Defendants' predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiff's business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Marketing Defendants. The predicate acts were committed or caused to be committed by the RICO Marketing Defendants through their participation in the Opioid Marketing Enterprise and in furtherance of its fraudulent scheme.

N. The Opioid Supply Chain Enterprise

367. Faced with the reality that they will now be held accountable for the consequences of the opioid epidemic they created, members of the industry resort to "a categorical denial of any criminal behavior or intent."[118] Defendants' actions went far beyond what could be considered ordinary business conduct. For more than a decade, certain Defendants, the "RICO Supply Chain Defendants" (all Defendants other than Walgreens, and Janssen) worked together in an illicit enterprise, engaging in conduct that was not only illegal, but in certain respects anti-competitive, with the common purpose and achievement of vastly increasing their respective profits and revenues by exponentially expanding a market that the law intended to restrict.

368. Knowing that dangerous drugs have a limited place in our society, and that their dissemination and use must be vigilantly monitored and policed to prevent the harm that drug abuse and addiction causes to individuals, society and governments, Congress enacted the Controlled Substances Act ("CSA"). Specifically, through the CSA, which created a closed system of distribution for controlled substances, Congress established an enterprise for good. CSA imposes a reporting duty that cuts across company lines. Regulations adopted under the CSA require that companies who are entrusted with permission to operate with within this system cannot simply operate as competitive in an "anything goes" profit-maximizing market. Instead, the statute tasks them to watch over each other with a careful eye for suspicious activity. Driven by greed, Defendants betrayed that trust and subverted the constraints of the CSA's closed system to conduct their own enterprise for evil.

[118] http://www.mckesson.com/about-mckesson/fighting-opioid-abuse/60-minutes-response (last visited, Apr. 21, 2018).

369. As "registrants" under the CSA, the RICO Supply Chain Defendants are duty bound to identify and report "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[119] Critically, these Defendants' responsibilities do not end with the products they manufacture or distribute—there is no such limitation in the law because their duties cut across company lines. Thus, when these Defendants obtain information about the sales and distribution of other companies' opioid products, as they did through data mining companies like IMS Health, they were legally obligated to report that activity to the DEA.

370. If morality and the law did not suffice, competition dictates that the RICO Supply Chain Defendants would turn in their rivals when they had reason to suspect suspicious activity. Indeed, if a manufacturer or distributor could gain market share by reporting a competitor's illegal behavior (causing it to lose a license to operate, or otherwise inhibit its activity), ordinary business conduct dictates that it would do so. Under the CSA this whistleblower or watchdog function is not only a protected choice, but a statutory mandate. Unfortunately, however, that is not what happened. Instead, knowing that investigations into potential diversion would only lead to shrinking markets, Defendants elected to operate in a conspiracy of silence, in violation of both the CSA and RICO.

371. The RICO Supply Chain Defendants' scheme required the participation of all. If any one member broke rank, its compliance activities would highlight deficiencies of the others, and the artificially high quotas they maintained through their scheme would crumble. But, if all the members of the enterprise conducted themselves in the same manner, it would be difficult for the DEA to go after any one of them. Accordingly, through the connections they made as a

[119] 21 C.F.R. 1301.74(b).

result of their participation in the Healthcare Distribution Alliance ("HDA"), the RICO Supply Chain Defendants chose to flout the closed system designed to protect the citizens. Publicly, in 2008, they announced their formulation of "Industry Compliance Guidelines: Reporting Suspicious Orders and Prevention Diversion of Controlled Substances." But, privately, Defendants refused to act and through their lobbying efforts, they collectively sought to undermine the impact of the CSA. Indeed, despite the issuance of these Industry Compliance Guidelines, which recognize these Defendants' duties under the law, as illustrated by the subsequent industry-wide enforcement actions and consent orders issued after that time, none of them complied. John Gray, President and CEO of the HDA said to Congress in 2014, it is "difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications." Yet, the RICO Supply Chain Defendants apparently all found the same profit-maximizing balance—intentionally remaining silent to ensure the largest possible financial return.

372. As described above, at all relevant times, the RICO Supply Chain Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues and profits by fraudulently increasing the quotas set by the DEA that would allow them to collectively benefit from a greater pool of prescription opioids to manufacture and distribute. In support of this common purpose and fraudulent scheme, the Defendants jointly agreed to disregard their statutory duties to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market so that those orders would not result in a decrease, or prevent an increase in, the necessary quotas.

373. At all relevant times, as described above, the RICO Supply Chain Defendants exerted control over, conducted and/or participated in the Opioid Supply Chain Enterprise by

fraudulently claiming that they were complying with their duties under the CSA to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, and to halt such unlawful sales, so as to increase production quotas and generate unlawful profits, as follows:

374. The RICO Supply Chain Defendants disseminated false and misleading statements to state and federal regulators claiming that:

a. the quotas for prescription opioids should be increased;

b. they were complying with their obligations to maintain effective controls against diversion of their prescription opioids;

c. they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids;

d. they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids; and

e. they did not have the capability to identify suspicious orders of controlled substances.

375. The Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."[120]

[120] *See HDMA is now the Healthcare Distribution Alliance*, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/; Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, WASHINGTON POST, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, WASHINGTON POST, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, CHARLESTON GAZETTE-MAIL, Feb. 18, 2017, http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-.

376. The CSA and the Code of Federal Regulations, require the RICO Supply Chain Defendants to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders. The failure to make reports as required by the CSA and Code of Federal Regulations amounts to a criminal violation of the statute.

377. The RICO Supply Chain Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other document required to be filed with the DEA including the Marketing Defendants' applications for production quotas. Specifically, the RICO Supply Chain Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

378. The RICO Supply Chain Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

379. In devising and executing the illegal scheme, the RICO Supply Chain Defendants devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts.

380. For the purpose of executing the illegal scheme, the RICO Supply Chain Defendants committed racketeering acts, which number in the thousands, intentionally and

knowingly with the specific intent to advance the illegal scheme. These racketeering acts, which included repeated acts of mail fraud and wire fraud, constituted a pattern of racketeering.

381. The RICO Supply Chain Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Marketing Defendants, the Distributor Defendants, or third parties that were foreseeably caused to be sent as a result of the Defendants' illegal scheme, including but not limited to:

a. The prescription opioids themselves;

b. Documents and communications that supported and/or facilitated the RICO Supply Chain Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;

c. Documents and communications that facilitated the manufacture, purchase and sale of prescription opioids;

d. RICO Supply Chain Defendants' DEA registrations;

e. Documents and communications that supported and/or facilitated RICO Supply Chain Defendants' DEA registrations;

f. RICO Supply Chain Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;

g. Documents and communications related to the RICO Supply Chain Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;

h. Documents intended to facilitate the manufacture and distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;

i. Documents for processing and receiving payment for prescription opioids;

j. Payments from the Distributors to the Marketing Defendants;

k. Rebates and chargebacks from the Marketing Defendants to the Distributors Defendants;

l. Payments to the RICO Supply Chain Defendants' lobbyists through the PCF;

m. Payments to the RICO Supply Chain Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;

n. Deposits of proceeds from the RICO Supply Chain Defendants' manufacture and distribution of prescription opioids; and

o. Other documents and things, including electronic communications.

382. The RICO Supply Chain Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce, including the following:

Defendant Group Name	**Company Names**	**Drugs**		
		Drug Name	**Chemical Name**	**CSA Schedule**
Purdue	(1) Purdue Pharma, LP, (2) Purdue Pharma, Inc., (3) The Purdue Frederick Company	OxyContin	Oxycodone hydrochloride extended release	Schedule II
		MS Contin	Morphine sulfate extended release	Schedule II
		Dilaudid	Hydromorphone hydrochloride	Schedule II
		Dilaudid-HP	Hydromorphone hydrochloride	Schedule II
		Butrans	Buprenorphine	Schedule II
		Hysinga ER	Hydrocodone bitrate	Schedule II
		Targiniq ER	Oxycodone hydrochloride	Schedule II
Teva	(1) Cephalon, Inc., (2) Teva Pharmaceutical Industries, Ltd., (3) Teva Pharmaceuticals USA, Inc.	Actiq	Fentanyl citrate	Schedule II
		Fentora	Fentanyl citrate	Schedule II
		Generic oxycontin	Oxycodone hydrochloride	Schedule II
Endo	(1) Endo Health Solutions, Inc., (2) Endo Pharmaceuticals Inc., (3) Qualitest	Opana ER	Oxymorphone hydrochloride extended release	Schedule II
		Opana	Oxymorphone hydrochloride	Schedule II

Defendant Group Name	**Company Names**	**Drugs**		
		Drug Name	**Chemical Name**	**CSA Schedule**
	Pharmaceuticals, Inc. (*wholly-owned subsidiary of Endo*)	Percodan	Oxymorphone hydrochloride and aspirin	Schedule II
		Percocet	Oxymorphone hydrochloride and acetaminophen	Schedule II
		Generic oxycodone		Schedule II
		Generic oxymorphone		Schedule II
		Generic hydromorphone		Schedule II
		Generic hydrocodone		Schedule II
Mallinckrodt	(1) Mallinckrodt PLC, (2) Mallinckrodt LLC (*wholly-owned subsidiary of Mallinckrodt PLC*)	Exalgo	Hydromorphone hydrochloride	Schedule II
		Roxicodone	Oxycodone hydrochloride	Schedule II
		Norco (Generic of Kadian)	Hydrocodone and acetaminophen	Schedule II
		Generic Duragesic	Fentanyl	Schedule II
		Generic Opana	Oxymorphone hydrochloride	Schedule II

383. Each of the RICO Supply Chain Defendants identified manufactured, shipped, paid for and received payment for the drugs identified above, throughout the United States.

384. The RICO Supply Chain Defendants used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the RICO Supply Chain Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

385. At the same time, the RICO Supply Chain Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids, and their compliance with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

386. The RICO Supply Chain Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

387. The RICO Supply Chain Defendants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail with each other and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

388. The mail and wire transmissions described herein were made in furtherance of the RICO Supply Chain Defendants' scheme and common course of conduct to deceive regulators, the public and the Plaintiff that these Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The RICO Supply Chain Defendants' scheme and common course of conduct was to increase or maintain high production quotas for their prescription opioids from which they could profit.

389. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden by Defendants and cannot be alleged without access to Defendants' books and records. However, Plaintiff has described the types of, and in some

instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

390. The RICO Supply Chain Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with these Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the RICO Supply Chain Defendants.

391. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

392. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiff's business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Supply Chain Defendants. The predicate acts were committed or caused to be committed by the Defendants through their participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.

393. As described above, the RICO Supply Chain Defendants were repeatedly warned, fined, and found to be in violation of applicable law and regulations, and yet they persisted. The sheer volume of enforcement actions against the Supply Chain Defendants supports this conclusion that the Supply Chain Defendants operated through a pattern and practice of willfully

and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74.

394. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims,Weymouth and the Weymouth Community. The RICO Supply Chain Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on this jurisdiction, its citizens or the Plaintiff. The RICO Supply Chain Defendants were aware that Plaintiff and the citizens of these jurisdictions rely on these Defendants to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

395. By intentionally refusing to report and halt suspicious orders of their prescription opioids, the RICO Supply Chain Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

IV. CAUSES OF ACTION

COUNT I
Public Nuisance
(Against All Defendants)

400. Weymouth incorporates the allegations within all other paragraphs of this Complaint as if fully set forth herein.

401. Each Defendant is liable for public nuisance because its conduct has caused an unreasonable and substantial interference with a right common to the general public, which is the proximate cause of, and/or substantial factor leading to, Weymouth's injury. *See* Restatement Second, Torts § 821B.

402. Defendants, individually and acting through their employees and agents, through fraudulent and deceptive marketing and/or other fraudulent schemes as described herein, created and maintained the opioid epidemic in Weymouth, which is harmful and disruptive to and unreasonably annoys, injures, endangers, and interferes with the public health, public safety, public peace, public comfort, and/or public convenience. The public nuisance caused by Defendants has significantly harmed Weymouth and a considerable number of its residents.

403. The Marketing Defendants fraudulently and deceptively marketed opioids. Further, Defendant Purdue misleadingly portrayed itself as cooperating with law enforcement and actively working to combat the opioid epidemic when, in reality, it failed to satisfy even the minimum, legally-required obligations to report suspicious prescribers.

404. In addition, by causing dangerously addictive drugs to flood the community, and to be diverted for illicit purposes, in contravention of federal and State law, each Defendant has injuriously affected rights common to the general public, specifically including the rights of the people of Weymouth to public health, safety, peace, comfort, and convenience. The public nuisance caused by Defendants' actions has caused substantial annoyance, inconvenience, and injury to the public.

405. By distributing and selling dangerously addictive opioid drugs not connected to a legitimate medical, scientific, or industrial purpose, all Defendants have committed a course of conduct that injuriously affects the safety, health, and morals of the people of Weymouth.

406. By failing to maintain a closed system that guards against diversion of dangerously addictive drugs for illicit purposes and by failing to report suspicious orders of opioids, Defendants injuriously affected public rights, including the right to public health, public safety, public peace, and public comfort of the people of Weymouth.

407. Defendants knowingly, intentionally, unlawfully, recklessly, and fraudulently manufacture, market, distribute, and sell prescription opioids that Defendants know, or reasonably should know, will produce widespread distribution of prescription opioids in and/or to Weymouth, resulting in addiction and abuse, an elevated level of crime, death, and injuries to the residents of Weymouth, a higher level of fear, discomfort, and inconvenience to the residents of Weymouth, and direct costs to Weymouth.

408. All Defendants' actions were, at the very least, a substantial factor in opioids becoming widely available and widely used in Weymouth. Defendants' actions were, at the very least, a substantial factor in deceiving doctors and patients about the risks and benefits of opioids for the treatment of chronic pain. Without Defendants' actions, opioid use, misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that now exists would have been averted.

409. Defendants knew of the public health hazard their conduct would create.

410. It was foreseeable to Defendants that their conduct would unreasonably interfere with the public health, public safety, public peace, public comfort, and/or public convenience.

411. Defendants' conduct is unreasonable, intentional, unlawful, reckless, or negligent.

412. Defendants' conduct is widespread and persistent, and creates substantial and ongoing harm. The harm inflicted outweighs any offsetting benefit. Defendants' conduct has caused deaths, serious injuries, and a severe disruption of public peace, health, order and safety. Defendants' ongoing and persistent misconduct is producing permanent and long-lasting damage.

413. Defendants had control over their conduct in Weymouth as is described in this Complaint, and that conduct has had an adverse effect on the public. Defendants had sufficient

control over, and responsibility for, the public nuisance they created—Defendants were in control of the "instrumentality" of the nuisance, namely prescription opioids, including the process of marketing, promotion, distribution, and creation and maintenance of the demand for prescription opioids at all relevant times.

414. Defendants' conduct and the opioid epidemic it created is likely to continue to cause significant harm to Weymouth and its residents.

415. Weymouth has suffered and continues to suffer special injuries distinguishable from those suffered by the general public. As discussed herein, it has incurred and continues to incur substantial costs from investigating, monitoring, policing, and remediating the opioid epidemic.

416. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. Weymouth alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

417. The public nuisance–i.e. the opioid epidemic–created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm and inconvenience can be abated.

WHEREFORE, Weymouth demands judgment in its favor against the Defendants for injunctive relief, abatement of the public nuisance, and for compensatory damages in an amount to be determined by a jury, together with prejudgment interest, post-judgment interest, costs and expenses, attorney fees, and such other relief as this Court deems just and equitable.

COUNT II
Violations of Massachusetts General Laws

Chapter 93A
(Against All Defendants)

418. Weymouth incorporates the allegations within all other paragraphs of this Complaint as if fully set forth herein.

419. Through the acts alleged herein Defendants engaged in deceptive trade practices in violation of Massachusetts law.

420. Defendants were and still are engaged in "trade" and "commerce" as defined by M.G.L. c. 93A, § 1.

421. Plaintiff was and is engaged in "trade" and "commerce" as defined by M.G.L. c. 93A, § 1.

422. The transactions, actions and inaction of Defendants, as described herein, constitutes unfair and deceptive acts and practices as defined by, and in violation of M.G.L. c. 93A, §§ 2, 11.

423. Defendants committed and continue to commit repeated and willful unfair or deceptive acts or practices, and unconscionable trade practices, in the conduct of commerce.

424. Each Defendant wrongfully represented that the opioid prescriptions they manufactured, marketed, and sold had characteristics, uses, or benefits that they do not have. These misrepresentations include but are not limited to the following:

a. Defendants' claims that the risks of long-term opioid use, especially the risk of addiction were overblown;

b. Defendants' claims that signs of addiction were "pseudoaddiction" reflecting undertreated pain, and should be responded to with *more* opioids;

c. Defendants' claims that opioid doses can be increased until pain relief is achieved and there is no ceiling dose;

d. Defendants' overstatement of the risks of NSAIDs, when compared to opioids;

e. Defendants' claims that evidence supports the long-term use of opioids for chronic pain;

f. Defendants' claims that screening tools effectively prevent addiction;

g. Defendants' claims that chronic opioid therapy would improve patients' function and quality of life;

h. Purdue's and Endo's claims that abuse-deterrent opioids prevent tampering and abuse;

i. Purdue's claims OxyContin provides a full 12 hours of pain relief;

j. Purdue's claims that it cooperates with and support efforts to prevent opioid abuse and diversion;

k. Teva's unsubstantiated claims that Actiq and Fentora were appropriate for treatment of non-cancer pain and its failure to disclose that Actiq and Fentora were not approved for such use; and

l. Defendants' use of front groups, to suggest that the deceptive statements from these sources described in this Complaint came from objective, independent sources.

425. The Defendants used exaggeration and/or ambiguity as to material facts and omitted and concealed material facts, which tended to deceive and/or did in fact deceive. The omissions and concealments of material fact include but are not limited to the following:

a. opioids are highly addictive and may result in overdose or death;

b. no credible scientific evidence supports the use of screening tools as a strategy for reducing abuse or diversion;

c. high dose opioids subject the user to greater risks of addiction, other injury, or death;

d. the risks of hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, and dizziness, increased falls and fractures in the

elderly, neonatal abstinence syndrome, and potentially fatal interactions with alcohol or benzodiazepines, particularly while exaggerating the risks of competing products, such as NSAIDs;

e. claims regarding the benefits of chronic opioid therapy lacked scientific support or were contrary to the scientific evidence;

f. Purdue's 12-hour OxyContin fails to last a full twelve hours in many patients;

g. Purdue and Endo's abuse-deterrent formulations are not designed to address, and have no effect on, the most common route of abuse (oral abuse), can be defeated with relative ease, and may increase overall abuse;

h. Defendants' failure to disclose their financial ties to and role in connection with KOLs and front groups.

426. The Defendants' omissions rendered even their seemingly truthful statements about opioids deceptive.

427. In addition, each Manufacturer and Distributor Defendant engaged in unfair and/or deceptive trade practices by failing to report suspicious orders of opioids and/or prevent the diversion of highly addictive prescription drugs to illegal sources.

428. Defendants failed to disclose the material facts that, *inter alia*, they were not in compliance with laws and regulations requiring that they maintain a system to prevent diversion, and specifically monitor, investigate, report, and refuse suspicious orders. But for these material factual omissions, Defendants would not have been able to sell or distribute opioids, and the Distributor Defendants would not have been able to receive and renew licenses to sell opioids.

429. Defendants' unfair, deceptive, and unconscionable misrepresentations, concealments, and omissions were reasonably calculated to deceive the public, the healthcare community, and the people of Weymouth.

430. Defendants acted knowingly, intentionally, and unlawfully.

431. Defendants' representations, concealments, and omissions constitute a willful course of conduct that continues to this day.

432. Without Defendants' unfair and/or deceptive trade practices, opioid use, misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that now exists would have been averted. Defendants' actions were immoral, unethical and unscrupulous and unlawfully caused the opioid epidemic in Massachusetts and in Weymouth.

433. Defendants' manufacturing, marketing, sales, and distribution practices unlawfully caused an opioid and heroin plague and epidemic in Weymouth. Each Defendant had a nondelegable duty to guard against and prevent the diversion of prescription opioids to other than legitimate channels.

434. The damages that Weymouth seeks to recover were sustained as a direct and proximate result of the Defendants' intentional and unlawful acts and omissions.

435. Weymouth seeks injunctive relief and economic losses resulting from Defendants' deceptive trade practices. Weymouth does not seek damages for physical personal injury or any physical damage to property caused by Defendants' actions.

436. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. Weymouth alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

WHEREFORE, Weymouth demands judgment against the Defendants in an amount to be determined at trial, with said amount doubled or trebled in accordance with the provisions of

Chapter 93A; and, that said judgment include an award of attorney's fees and costs; and for such other relief as this Court deems just and equitable.

COUNT III
Negligence and Negligent Misrepresentation
(Against All Defendants)

437. Weymouth incorporates the allegations within all other paragraphs of this Complaint as if fully set forth herein.

438. To establish actionable negligence, Weymouth must show, in addition to the existence of a duty, a breach of that duty and injury resulting proximately therefrom. All such elements exist here.

439. Defendants have a duty to exercise reasonable care in manufacturing, marketing, distributing, and selling highly dangerous opioid drugs.

440. Defendants have a duty to exercise reasonable care under the circumstances. This includes a duty not to cause foreseeable harm to others. In addition, Defendants, having engaged in conduct that created an unreasonable risk of harm to others, had, and still have, a duty to exercise reasonable care to prevent the threatened harm.

441. Manufacturing Defendants repeatedly breached their duties by deceptively marketing opioids as described herein, including minimizing their risks, such as the risks of addiction and overdose, and exaggerating the purported benefits of long-term use of opioids for the treatment of chronic pain. Manufacturing Defendants omitted or concealed material facts and failed to correct prior misrepresentations and omissions about the risks and benefits of opioids. These Defendants' omissions rendered even their seemingly truthful statements about opioids deceptive.

442. Distributor Defendants breached their duties to exercise due care in the business of wholesale distribution of dangerous opioids, which are Schedule II Controlled Substances, by failing to monitor for, failing to report, and filling highly suspicious orders time and again. Because the purpose of these duties was to prevent the resulting harm – misuse and/or diversion of highly addictive drugs for non-medical purposes–the causal connection between Defendants' breach of duties and the ensuing harm was entirely foreseeable.

443. The Distributor Defendants misrepresented their compliance with their duties under the law and concealed their noncompliance and shipments of suspicious orders of opioids to Weymouth and destinations from which they knew opioids were likely to be diverted into Weymouth, in addition to other misrepresentations alleged and incorporated herein.

444. All Defendants breached their duties to prevent diversion and report and halt suspicious orders, and all Defendants misrepresented their compliance with their legal duties.

445. Defendants' breaches were intentional and/or unlawful, and Defendants' conduct was willful, wanton, malicious, reckless, oppressive, and/or fraudulent.

446. The foreseeable harm from a breach of these duties is the abuse and diversion of prescription opioids, and addiction, overdose, and death in the Weymouth community.

447. Reasonably prudent manufacturers of pharmaceutical products would know that deceptively and misleadingly marketing highly addictive opioids for chronic pain would result in the severe harm of addiction, foreseeably causing patients to seek increasing levels of opioids and to turn to the illegal drug market as a result of a drug addiction that was foreseeable to the Defendants. Reasonably prudent manufacturers and distributors would know that failing to report suspicious orders and prescribing, particularly while assuring the public of their

commitment to fighting the opioid epidemic, would exacerbate problems of diversion and non-medical use of prescription opioids.

448. Reasonably prudent manufacturers and distributors of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities and the significant costs which would be imposed upon the governmental entities associated with those communities. The closed system of opioid distribution whereby all links in the chain have a duty to prevent diversion exists for the purpose of controlling dangerous substances, such as opioids, and preventing diversion and abuse.

449. These Defendants' breach of the duties described herein directly and proximately resulted in the injuries and damages alleged by Weymouth.

450. Weymouth seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from the negligence of Defendants. It does not seek damages which may have been suffered by individual citizens of Weymouth for wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by the actions of Defendants

451. The misconduct alleged in this case is ongoing and persistent.

452. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. Weymouth alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

WHEREFORE, Weymouth demands judgment in its favor against the Defendants for compensatory damages in an amount to be determined by a jury and punitive damages, together

with prejudgment interest, post-judgment interest, costs and expenses, attorney fees, and such other relief as this Court deems just and equitable.

COUNT IV
Fraud and Fraudulent Misrepresentation
(Against All Defendants)

453. Weymouth incorporates the allegations within all other paragraphs of this Complaint as if fully set forth herein.

454. Defendants, individually and acting through their employees and agents, knowingly and intentionally made misrepresentations and omissions of facts material to Weymouth, and its residents and medical professionals to induce them to purchase, administer, and consume opioids as set forth in detail above.

455. Manufacturing Defendants' fraudulent misrepresentations are detailed in this Complaint and include overstating the benefits of and evidence for the use of opioids for chronic pain and understating their very serious risks; including the risk of addiction, falsely promoting abuse-deterrent formulations as reducing abuse, falsely claiming that OxyContin provides 12 hours of relief, and falsely portraying their efforts or commitment to rein in the diversion and abuse of opioids.

456. Defendants' omissions, which were false and misleading in their own right, rendered even seemingly truthful statements about opioids false and misleading and likely to mislead Weymouth prescribers and consumers.

457. All Defendants made false statements regarding their compliance with state and federal law regarding their duties to monitor, report, and halt suspicious orders and to prevent diversion, and/or they concealed their noncompliance with these requirements.

458. Defendants knew at the time that they made their misrepresentations and omissions that they were false.

459. Defendants knew or should have known that Weymouth would be adversely impacted economically by their misrepresentations in that citizens of Weymouth would become addicted to the Defendants' opioids which, in turn, would cause Weymouth to expend funds on emergency response; law enforcement, social services, and other municipal services to care for their citizens, thereby proximately causing Weymouth injuries and damages. As such, the Defendants owed a duty of care to Weymouth.

460. Defendants' false representations and concealments were reasonably calculated to deceive Weymouth and its residents and the physicians who prescribed and the patients who took opioids in Weymouth, were made with the intent to deceive, and did in fact deceive these persons and Weymouth.

461. Defendants intended for Weymouth, its residents, and health care providers to rely on their misrepresentations and omissions, and knew that such reliance would cause Weymouth to suffer loss.

462. Weymouth and healthcare providers and residents in Weymouth reasonably relied on Defendants' misrepresentations and omissions in writing, filling, using, and paying for prescriptions for Defendants' opioids. As a result of Defendants' fraudulent misrepresentations, the use of Defendants' opioid medicines became widespread and continuous, and resulted in the scourge of addiction, overdose, and death that is plaguing the country and Weymouth.

463. Weymouth suffered actual pecuniary damages proximately caused by Defendants' misrepresentations and omissions of material fact, which include expending additional funds on

emergency response, law enforcement, social services, and other municipal services that Weymouth otherwise would not have incurred.

464. Weymouth seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from the fraud of Defendants. It does not seek damages which may have been suffered by individual citizens of Weymouth for wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by the actions of Defendants.

465. The fraud alleged in this case is ongoing and persistent.

466. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. Weymouth alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

WHEREFORE, Weymouth demands judgment in its favor against the Defendants for compensatory damages in an amount to be determined by a jury and punitive damages, together with prejudgment interest, post-judgment interest, costs and expenses, attorney fees, and such other relief as this Court deems just and equitable.

COUNT V
Unjust Enrichment
(Against All Defendants)

467. Weymouth incorporates the allegations within all other paragraphs of this Complaint as if fully set forth herein.

468. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from the increase in the distribution and

purchase of opioids within Weymouth, including from opioids foreseeably and deliberately diverted within and into Weymouth.

469. Weymouth has expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Defendants' conduct.

470. These expenditures include the provision of healthcare services and benefits, emergency services, social services, and other services in excess of what would normally be provided were it not for the opioid epidemic.

471. These expenditures have helped sustain Defendants' businesses.

472. Weymouth has conferred a benefit upon Defendants by paying for Defendants' externalities: the cost of the harms caused by Defendants' improper marketing practices.

473. Defendants were aware of these obvious benefits, and their retention of the benefit is unjust.

474. Weymouth has paid for the cost of Defendants' externalities and Defendants have benefited from those payments because they allowed them to continue providing customers with a high volume of opioid products. Because of their deceptive marketing of prescription opioids and improper and excessive distribution of prescription opioids, Defendants obtained enrichment they would not otherwise have obtained. The enrichment was without justification and Weymouth lacks a remedy provided by law.

475. Defendants have unjustly retained benefits to the detriment of Weymouth, and Defendants' retention of such benefits violates the fundamental principles of justice, equity, and good conscience.

476. Defendants' misconduct alleged in this case is ongoing and persistent.

477. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. Weymouth alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

478. Weymouth has incurred expenditures for special programs over and above its ordinary public services.

WHEREFORE, Weymouth seeks all legal and equitable relief as allowed by law, including disgorgement of Defendants' unjust enrichment, benefits, and ill-gotten gains, plus interest, acquired as a result of the unlawful or wrongful conduct alleged herein pursuant to common law and such other relief as this Court deems just and equitable.

COUNT VI
Violation of RICO, 18 U.S.C. § 1961 et seq. – Opioid Marketing Enterprise
(Against Purdue, Teva, Janssen, and Endo (the "RICO Marketing Defendants"))

479. Weymouth incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

480. The RICO Marketing Defendants—through the use of "Front Groups" that appeared to be independent of the RICO Marketing Defendants through the dissemination of publications that supported the RICO Marketing Defendants' scheme, through continuing medical education ("CME") programs controlled and/or funded by the RICO Marketing Defendants, by the hiring and deployment of KOLs, who were paid by the RICO Marketing Defendants to promote their message, and through the "detailing" activities of the RICO Marketing Defendants' sales forces—conducted an association-in-fact enterprise, and/or participated in the conduct of an enterprise through a pattern of illegal activities (the predicate

racketeering acts of mail and wire fraud) to carry-out the common purpose of the Opioid Marketing Enterprise, i.e., to unlawfully increase profits and revenues from the continued prescription and use of opioids for long-term chronic pain. Through the racketeering activities of the Opioid Marketing Enterprise, the RICO Marketing Defendants sought to further the common purpose of the enterprise through a fraudulent scheme to change prescriber habits and public perception about the safety and efficacy of opioid use by convincing them that each of the nine false propositions alleged earlier were true. In so doing, each of the RICO Marketing Defendants knowingly conducted and participated in the conduct of the Opioid Marketing Activities by engaging in mail and wire fraud in violation of 18 U.S.C. §§ 1962(c) and (d).

481. The Opioid Marketing Enterprise alleged above, is an association-in-fact enterprise that consists of the RICO Marketing Defendants (Purdue, Teva, Janssen, and Endo); the Front Groups (APF, AAPM, APS, and FSMB); and the KOLs (Dr. Portenoy, Dr. Webster, Dr. Fine, and Dr. Fishman).

482. Each of the RICO Marketing Defendants and the other members of the Opioid Marketing Enterprise conducted and participated in the conduct of the Opioid Marketing Enterprise by playing a distinct role in furthering the enterprise's common purpose of increasing profits and sales through the knowing and intentional dissemination of false and misleading information about the safety and efficacy of long-term opioid use, and the risks and symptoms of addiction, in order increase the market for prescription opioids by changing prescriber habits and public perceptions and increase the market for opioids.

483. Specifically, the RICO Marketing Defendants each worked together to coordinate the enterprise's goals and conceal their role, and the enterprise's existence, from the public by, among other things, (i) funding, editing and distributing publications that supported and

advanced their false messages; (ii) funding KOLs to further promote their false messages; (iii) funding, editing and distributing CME programs to advance their false messages; and (iv) tasking their own employees to direct deceptive marketing materials and pitches directly at physicians and, in particular, at physicians lacking the expertise of pain care specialists (a practice known as sales detailing).

484. Each of the Front Groups helped disguise the role of RICO Marketing Defendants by purporting to be unbiased, independent patient-advocacy and professional organizations in order to disseminate patient education materials, a body of biased and unsupported scientific "literature," and "treatment guidelines" that promoted the RICO Marketing Defendants false messages.

485. Each of the KOLs were physicians chosen and paid by each of the RICO Marketing Defendants to influence their peers' medical practice by promoting the Marketing Defendants' false message through, among other things, writing favorable journal articles and delivering supportive CMEs as if they were independent medical professionals, thereby further obscuring the RICO Marketing Defendants' role in the enterprise and the enterprise's existence.

486. Further, each of the RICO Marketing Defendants, KOLs and Front Groups that made-up the Opioid Marketing Enterprise had systematic links to and personal relationships with each other through joint participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities. The systematic links and personal relationships that were formed and developed allowed members of the Opioid Marketing Enterprise the opportunity to form the common purpose and agree to conduct and participate in the conduct of the Opioid Marketing Enterprise. Specifically, each of the RICO Marketing Defendants coordinated their efforts through the same KOLs and Front Groups, based

on their agreement and understanding that the Front Groups and KOLs were industry friendly and would work together with the RICO Marketing Defendants to advance the common purpose of the Opioid Marketing Enterprise; each of the individuals and entities who formed the Opioid Marketing Enterprise acted to enable the common purpose and fraudulent scheme of the Opioid Marketing Enterprise.

487. At all relevant times, the Opioid Marketing Enterprise: (a) had an existence separate and distinct from each Marketing Defendant and its members; (b) was separate and distinct from the pattern of racketeering in which the RICO Marketing Defendants engaged; (c) was an ongoing and continuing organization consisting of individuals, persons, and legal entities, including each of the RICO Marketing Defendants; (d) was characterized by interpersonal relationships between and among each member of the Opioid Marketing Enterprise, including between the RICO Marketing Defendants and each of the Front Groups and KOLs; and (e) had sufficient longevity for the enterprise to pursue its purpose and functioned as a continuing unit.

488. The persons and entities engaged in the Opioid Marketing Enterprise are systematically linked through contractual relationships, financial ties, personal relationships, and continuing coordination of activities, as spearheaded by the RICO Marketing Defendants.

489. The RICO Marketing Defendants conducted and participated in the conduct of the Opioid Marketing Enterprise through a pattern of racketeering activity that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud), to increase profits and revenue by changing prescriber habits and public perceptions in order to increase the prescription and use of prescription opioids, and expand the market for opioids.

490. The RICO Marketing Defendants each committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e.

violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Marketing Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the RICO Marketing Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Marketing Enterprise, the U.S. Mail and interstate wire facilities. The RICO Marketing Defendants participated in the scheme to defraud by using mail, telephones and the Internet to transmit mailings and wires in interstate or foreign commerce.

491. The RICO Marketing Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

a. Mail Fraud: The RICO Marketing Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

b. Wire Fraud: The RICO Marketing Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

492. The RICO Marketing Defendants used the mail and wires to send or receive thousands of communications, publications, representations, statements, electronic transmissions and payments to carry-out the Opioid Marketing Enterprise's fraudulent scheme.

493. Because the RICO Marketing Defendants disguised their participation in the enterprise, and worked to keep even the enterprise's existence secret so as to give the false appearance that their false messages reflected the views of independent third parties, many of the precise dates of the Opioid Marketing Enterprise's uses of the U.S. Mail and interstate wire facilities (and corresponding predicate acts of mail and wire fraud) have been hidden and cannot

be alleged without access to the books and records maintained by the RICO Marketing Defendants, Front Groups, and KOLs. Indeed, an essential part of the successful operation of the Opioid Marketing Enterprise alleged herein depended upon secrecy. However, Weymouth has described the occasions on which the RICO Marketing Defendants, Front Groups, and KOLs disseminated misrepresentations and false statements to Weymouth consumers, prescribers, and regulators, and how those acts were in furtherance of the scheme.

494. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Weymouth consumers, prescribers, regulators and Weymouth. The RICO Marketing Defendants, Front Groups and KOLs calculated and intentionally crafted the scheme and common purpose of the Opioid Marketing Enterprise to ensure their own profits remained high. In designing and implementing the scheme, the RICO Marketing Defendants understood and intended that those in the distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and scientific evidence regarding the RICO Marketing Defendants' products.

495. The RICO Marketing Defendants' pattern of racketeering activity alleged herein and the Opioid Marketing Enterprise are separate and distinct from each other. Likewise, the RICO Marketing Defendants are distinct from the Opioid Marketing Enterprise.

496. The pattern of racketeering activity alleged herein is continuing as of the date of this complaint, and, upon information and belief, will continue into the future unless enjoined by this Court.

497. The racketeering activities conducted by the RICO Marketing Defendants, Front Groups and KOLs amounted to a common course of conduct, with a similar pattern and purpose,

intended to deceive Weymouth consumers, prescribers, regulators and Weymouth. Each separate use of the U.S. Mail and/or interstate wire facilities employed by Defendants was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Weymouth consumers, prescribers, regulators and Weymouth. The RICO Marketing Defendants have engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the Opioid Marketing Enterprise.

498. Each of the RICO Marketing Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

499. As described herein, the RICO Marketing Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant money and revenue from the marketing and sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

500. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

501. The RICO Marketing Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Weymouth injury in their business and property. The RICO Marketing Defendants' pattern of racketeering activity logically,

substantially and foreseeably caused an opioid epidemic. Weymouth's injuries, as described below, were not unexpected, unforeseen or independent. Rather, as Weymouth alleges, the RICO Marketing Defendants knew that the opioids were unsuited to treatment of long-term chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse. Nevertheless, the RICO Marketing Defendants engaged in a scheme of deception that utilized the mail and wires in order to carry-out the Opioid Marketing Enterprises' fraudulent scheme, thereby increasing sales of their opioid products.

502. It was foreseeable and expected that the RICO Marketing Defendants creating and then participating in the Opioid Marketing Enterprise through a pattern of racketeering activities to carry-out their fraudulent scheme would lead to a nationwide opioid epidemic, including increased opioid addiction and overdose.

503. Specifically, the RICO Marketing Defendants' creating and then participating in the Opioid Marketing Enterprise through a pattern of racketeering activities to carry-out their fraudulent scheme has injured Weymouth in the form of substantial losses of money and property that logically, directly and foreseeably arise from the opioid-addiction epidemic. Weymouth's injuries, as alleged throughout this complaint, and expressly incorporated herein by reference, include but are not limited to:

a. Losses caused by the decrease in funding available for Weymouth's public services for which funding was lost because it was diverted to other public services designed to address the opioid epidemic;

b. Costs of training emergency and/or first responders in the proper handling of drugs such as fentanyl, and the proper treatment of drug overdoses;

c. Costs associated with providing police officers, firefighters, and emergency and/or first responders with Naloxone–an opioid antagonist used to block the deadly effects of opioids in the context of overdose;

d. Costs associated with emergency responses by police officers, firefighters, and emergency and/or first responders to opioid overdoses;

e. Costs associated with law enforcement and public safety relating to the opioid epidemic, including but not limited to attempts to stop the flow of opioids into local communities, to arrest and prosecute street-level dealers, to prevent the current opioid epidemic from spreading and worsening, and to deal with the increased levels of crimes that have directly resulted from the increased homeless and drug-addicted population; and

f. Costs associated with Weymouth educational programs and support groups related to the opioid epidemic.

504. Weymouth's injuries were directly and thus proximately caused by these Defendants' racketeering activities because they were the logical, substantial and foreseeable cause of Weymouth's injuries. But for the opioid-addiction epidemic the RICO Marketing Defendants created through their Opioid Marketing Enterprise, Weymouth would not have lost money or property.

505. Weymouth is the most directly harmed entity and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

WHEREFORE, Weymouth seeks all legal and equitable relief as allowed by law, including, inter alia, actual damages; treble damages; equitable and/or injunctive relief in the form of court-supervised corrective communication, actions and programs; forfeiture as deemed proper by the Court; attorney's fees; all costs and expenses of suit; and pre- and post-judgment interest.

COUNT VII
Violation of RICO, 18 U.S.C. § 1961 et seq. – Opioid Supply Chain Enterprise (Against Purdue, Teva, Endo, Mallinckrodt, McKesson, Cardinal, and AmerisourceBergen (the "RICO Supply Chain Defendants"))

506. Weymouth incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

507. At all relevant times, the RICO Supply Chain Defendants were and are "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

508. The RICO Supply Chain Defendants together formed an association-in-fact enterprise, the Opioid Supply Chain Enterprise, for the purpose of increasing the quota for and profiting from the increased volume of opioid sales in the United States. The Opioid Supply Chain Enterprise is an association-in-fact enterprise within the meaning of § 1961. The Opioid Supply Chain Enterprise consists of the RICO Supply Chain Defendants.

509. The RICO Supply Chain Defendants were members the Healthcare Distribution Alliance (the "HDA"). Each of the RICO Supply Chain Defendants is a member, participant, and/or sponsor of the HDA, and has been since at least 2006, and utilized the HDA to form the interpersonal relationships of the Opioid Supply Chain Enterprise and to assist them in engaging in the pattern of racketeering activity that gives rise to the Count.

510. At all relevant times, the Opioid Supply Chain Enterprise: (a) had an existence separate and distinct from each of the RICO Supply Chain Defendants; (b) was separate and distinct from the pattern of racketeering in which the RICO Supply Chain Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the RICO Supply Chain Defendants; (d) was characterized by interpersonal relationships among the RICO Supply Chain Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit. Each member of the Opioid Supply Chain Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid quotas and resulting sales.

511. The RICO Supply Chain Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators, and the American public by knowingly conducting or participating in the conduct of the Opioid Supply Chain Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

512. The RICO Supply Chain Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Supply Chain Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the RICO Supply Chain Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Supply Chain Enterprise. The RICO Supply Chain Defendants participated in the scheme to defraud by using mail, telephone and the Internet to transmit mailings and wires in interstate or foreign commerce.

513. The RICO Supply Chain Defendants also conducted and participated in the conduct of the affairs of the Opioid Supply Chain Enterprise through a pattern of racketeering activity by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

514. The RICO Supply Chain Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 843(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in,

or omit any material information from, any application, report, record or other document required to be made, kept or filed under this subchapter. A violation of § 843(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 843(d)(1).

515. Each of the RICO Supply Chain Defendants is a registrant as defined in the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

a. The RICO Supply Chain Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to: Mail Fraud: The RICO Supply Chain Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

b. Wire Fraud: The RICO Supply Chain Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

c. Controlled Substance Violations: The Distribution Defendants violated 21 U.S.C. § 823 by knowingly or intentionally furnishing false or fraudulent information in, and/or omitting material information from, documents filed with the DEA.

516. The RICO Supply Chain Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

517. The RICO Supply Chain Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

518. The RICO Supply Chain Defendants hid from the general public and suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities about the

reality of the suspicious orders that the RICO Supply Chain Defendants were filling on a daily basis – leading to the diversion of hundreds of millions of doses of prescriptions opioids into the illicit market.

519. The RICO Supply Chain Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

520. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding manufacturing prescription opioids and refusing to report suspicious orders.

521. As described herein, the RICO Supply Chain Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

522. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured Weymouth's business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Supply Chain Defendants. The predicate acts were committed or caused to be committed by the RICO Supply Chain Defendants through their participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.

523. The pattern of racketeering activity alleged herein and the Opioid Supply Chain Enterprise are separate and distinct from each other. Likewise, Defendants are distinct from the enterprise.

524. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

525. Many of the precise dates of the RICO Supply Chain Defendants' criminal actions at issue here have been hidden by Defendants and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Supply Chain Enterprise alleged herein depended upon secrecy.

526. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

527. It was foreseeable to Defendants that Weymouth would be harmed when they refused to report and halt suspicious orders, because their violation of the duties imposed by the CSA and Code of Federal Regulations allowed the widespread diversion of prescription opioids out of appropriate medical channels and into the illicit drug market – causing the opioid epidemic that the CSA intended to prevent.

528. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

529. The RICO Supply Chain Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Weymouth's injury in its business and property. The RICO Supply Chain Defendants' pattern of racketeering activity, including their refusal to identify, report and halt suspicious orders of controlled substances, logically, substantially and foreseeably caused an opioid epidemic. Weymouth was injured by the RICO

Supply Chain Defendants' pattern of racketeering activity and the opioid epidemic that they created.

530. The RICO Supply Chain Defendants knew that the opioids they manufactured and supplied were unsuited to treatment of long-term, chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse. Nevertheless, the RICO Supply Chain Defendants engaged in a scheme of deception, that utilized the mail and wires as part of their fraud, in order to increase sales of their opioid products by refusing to identify, report suspicious orders of prescription opioids that they knew were highly addictive, subject to abuse, and were actually being diverted into the illegal market.

531. The RICO Supply Chain Defendants' predicate acts and pattern of racketeering activity were a cause of the opioid epidemic which has injured Weymouth in the form of substantial losses of money and property that logically, directly and foreseeably arise from the opioid-addiction epidemic.

532. Specifically, Weymouth's injuries, as alleged throughout this complaint, and expressly incorporated herein by reference, include but are not limited to:

a. Losses caused by the decrease in funding available for Weymouth's public services for which funding was lost because it was diverted to other public services designed to address the opioid epidemic;

b. Costs of training emergency and/or first responders in the proper handling of drugs such as fentanyl, and the proper treatment of drug overdoses;

c. Costs associated with providing police officers, firefighters, and emergency and/or first responders with Naloxone–an opioid antagonist used to block the deadly effects of opioids in the context of overdose;

d. Costs associated with emergency responses by police officers, firefighters, and emergency and/or first responders to opioid overdoses;

e. Costs associated with law enforcement and public safety relating to the opioid epidemic, including but not limited to attempts to stop the flow of opioids into

local communities, to arrest and prosecute street-level dealers, to prevent the current opioid epidemic from spreading and worsening, and to deal with the increased levels of crimes that have directly resulted from the increased homeless and drug-addicted population; and

f. Costs associated with Weymouth educational programs and support groups related to the opioid epidemic.

533. Weymouth's injuries were proximately caused by Defendants' racketeering activities because they were the logical, substantial and foreseeable cause of Weymouth's injuries. But for the opioid-addiction epidemic created by Defendants' conduct, Weymouth would not have lost money or property.

534. Weymouth's injuries were directly caused by the RICO Supply Chain Defendants' pattern of racketeering activities.

535. Weymouth is most directly harmed and there are no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

WHEREFORE, Weymouth seeks all legal and equitable relief as allowed by law, including, inter alia, actual damages; treble damages; equitable and/or injunctive relief in the form of court-supervised corrective communication, actions and programs; forfeiture as deemed proper by the Court; attorney's fees; all costs and expenses of suit; and pre- and post-judgment interest.

V. PRAYER FOR RELIEF

WHEREFORE, Weymouth requests the following relief:

A. A finding that, by the acts alleged herein, Defendants have created a public nuisance;

B. An injunction permanently enjoining Defendants from engaging in the acts and practices that caused the public nuisance;

C. An order directing Defendants to abate and pay damages for the public nuisance;

D. A finding that Defendants engaged in unfair and deceptive trade practices in violation of M.G.L. c. 93A, §§ 2 and 11;

E. A finding that by the acts alleged herein, the Defendants were negligent and grossly negligent, and that Defendants engaged in fraudulent misrepresentations;

F. Compensatory damages in an amount sufficient to fairly and completely compensate for all damages alleged herein;

G. Punitive damages;

H. Disgorgement of Defendants' unjust enrichment, benefits, and ill-gotten gains, plus interest, acquired as a result of the unlawful or wrongful conduct alleged herein;

I. Treble or multiple damages and civil penalties as allowed by statute;

J. For costs, filing fees, pre and post judgment interest, and attorney's fees; and;

K. For all other relief at law or in equity, deemed just by this Court.

PLAINTIFF DEMANDS A TRIAL BY JURY AS TO ALL ISSUES SO TRIABLE.

Respectfully submitted,

TOWN OF WEYMOUTH
By its attorneys,

/s/ Kate R. Cook

Kate R. Cook (BBO #650698)
Gwen Nolan King (BBO # 673878)
cook@sugarmanrogers.com
king@sugarmanrogers.com
SUGARMAN, ROGERS, BARSHAK & COHEN
101 Merrimac Street
Boston, MA 02114
617.227.3030

-and-

Linda Singer*
Elizabeth Smith*
Sara D. Aguiñiga*
lsinger@motleyrice.com
esmith@motleyrice.com
saguiniga@motleyrice.com
MOTLEY RICE LLC
401 9th Street NW, Suite 1001
Washington, D.C. 20004
(202) 386-9626
** Pro hac vice applications to be submitted.*

-and-

Joseph Callanan, (BBO # 648397)
jcallanan@weymouth.ma.us
Town Solicitor
Weymouth Town Hall
75 Middle Street, Third Floor
Weymouth, Massachusetts 02189
(781) 682-3503

Counsel for Plaintiff Town of Weymouth

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